SASTRA

Reg. No. ECR/324/indt/DL/2020

Society for Academic, Scientific & Translational Research Advancement (SASTRA)
Ethics Committittee For Clinical Trials

Registered with Central Drugs Standards Control Organization, Ministry of Health & Family Welfare, Govt. of India

Letter No: SEC/ASZ/2020-005

Date: 29 Dec 2020

To

Dr. V.K. Garg,
Principal Investigator,
Prof. & HOD (Dermatology)
Santosh Medical College Hospital,
#1, Ambedkar Road, Ghaziabad,
Uttar Pradesh-201001

Reference: Your letter No.- Nil, sign Dated- 10 Dec 2020, received by this office vide inward no. 03 on 11 Dec 2020.

Subject: Approval to conduct Phase III Clinical Study at Santosh Medical College Hospital, Ghaziabad - reg.

Dear Dr. V.K. Garg,

The Society for Academic Scientific & Translational Research Advancement (SASTRA) Independent Ethics Committee reviewed and discussed your application to conduct the clinical trial entitled "**Protocol Title: A phase III, multicentric, randomized, double blind, parallel group, comparative, clinical study to evaluate the efficacy and safety of bilastine tablets 40 mg for the treatment of chronic spontaneous urticaria.**" In the meeting of Ethics Committee held on 19th Dec. 2020.

The following documents were reviewed:

(a) Trial protocol ID: ICS/SYN/2020/001), Dated:24 Jun 2020, version No. 2.0.
(b) Patient information sheet and informed consent form in English (version: 1.1 dated 15 Oct 2020) and Hindi (Version 1.1 dated: 17 Oct 2020) language.
(c) Investigator's brochure, dated 24 Jun 2020, Version No. 2.0
(d) Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.

(e) Principal investigator's current Curriculum Vitae.

(f) Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.

(g) Investigator's agreement with the sponsor.

(h) Investigator's undertaking.

(i) Insurance Policy for Clinical Trial Proposal

The following members of the ethics committee were present at the meeting held on 19th Dec. 2020 from 02:30 PM to 04:00 PM at Rohini, Delhi and also via video conferencing.

1.	DR. CHAKRA DHAR TRIPATHI	Chairperson
2.	Ms. SHWETA SAHNI	Member Secretary
3.	DR. VIJAY KUMAR GARG	Clinician
4.	DR. KIRAN CHHABRA	Clinician
5.	Dr. MEGHA VIJ	Basic Medical Scientist
6.	Mr. ALI SARDAR ZAIDI	Legal Expert
7.	Ms. ISHA THAKUR	Legal Expert
8.	Mr. NIRAJ SINGH YADAV	Member
9.	Dr. ASHISH RANJAN	Social Scientist
10.	Mr. SATISH KAPOOR	Social Scientist
11.	Ms. SHALINI SHEKHAR	Lay Person

We approve the trial to be conducted in its presented form.

REGISTRAR

Conditions of Approval:

The Ethics Committee to be informed about the following:

- Progress of the study at routine interval,
- Any Serious Adverse Events (SAE) occurring in the course of the study,
- Any changes in the protocol and patient information or informed consent and to be provided with a copy of the final report.
- **Final executed Clinical Trial Agreement to be notified to EC.**

Yours sincerely,

Shweta Sahni

Digitally signed by Shweta Sahni
DN: c=IN, pn=Personal, title=9987, pseudonym=ec2f774ee76bcf39ff4450cef9a80fed8c3cf26, 2.5.4.20=a69473bf065a3741222929cae6bb4a210c1d7ba7e1cb2863e2a69966c3e4735c9b, postalCode=110085, st=Delhi, serialNumber=382bd2ac34e74bcc7c59adbe720bb9fb47d5307a606a4c864db085d3f72e7786e, cn=Shweta Sahni
Date: 2020.12.29 19:56:27 +05'30'

Member Secretary,

SASTRA Ethics Committee

Clinical Trial Details (PDF Generation Date :- Wed, 06 Jan 2021 09:39:38 GMT)

CTRI Number	CTRI/2020/11/029215 [Registered on: 18/11/2020] - **Trial Registered Prospectively**
Last Modified On	30/12/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	To evaluate the effectiveness and safety of non sedating anti allergics for the treatment of Chronic Spontaneous Urticaria
Scientific Title of Study	A Phase III Multicentric Randomized Double Blind Parallel Group Comparative Clinical Study to Evaluate the Efficacy and Safety of Bilastine Tablets 40 mg for the Treatment of Chronic Spontaneous Urticaria

Secondary IDs if Any

Secondary ID	Identifier
ICS/SYN/2020-001 Version 2.0 Dated 24 Jun 2020	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr R M Chhabra
Designation	Medical Monitor
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr R M Chhabra
Designation	Medical Monitor

Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Synokem Pharmaceuticals Ltd 14/486, Sunder Vihar, Outer Ring Road, Paschim Vihar, New Delhi - 110087

Primary Sponsor

Primary Sponsor Details	
Name	Synokem Pharmaceuticals Ltd
Address	14/486, Sunder Vihar, Outer Ring Road, Paschim Vihar, New Delhi - 110087, India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Anjeeta Dhawan	Jaipur Golden Hospital	Room # 04, Derma Division, Department of Dematology, 02, Institutional Area, Sector III, Rohini, Delhi 110085 North West DELHI North West DELHI	011-27907000 011-27907000 JGHDSMO@Gmail.com
Dr M Sendhil Kumaran	Postgraduate Institute of Medical Education and Research	Department of Dermatology, Venerology & Leprology, PGIMER Chandigarh CHANDIGARH	0172-2756561 0172-2745078 Sendhil1974@icloud.com
Dr Vijay Kumar Garg	Santosh Medical College Hospital	Santosh Medical College Hospital#1, Ambedkar Road Ghaziabad UTTAR PRADESH	0120-2741141 0120-2741141 smchgzb@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee	Not Applicable	No Date Specified	No
Society for Academic, Scientific &	Approved	31/10/2020	Yes

Translational Research Advancement			
Society for Academic, Scientific & Translational Research Advancement	Approved	29/12/2020	Yes

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	14/09/2020

Health Condition / Problems Studied

Health Type	Condition
Patients	Idiopathic urticaria

Intervention / Comparator Agent

Type	Name	Details
Intervention	Bilastine 40 mg Tablets	Bilastine 40 mg Tablets Once daily for 28 Days
Comparator Agent	Bilastine 20 mg Tablets	Bilastine 20 mg Tablets Once daily for 28 Days
Comparator Agent	Levocetrizine 10 mg Tablets	Levocetrizine 10 mg Tablets Once daily for 28 Days

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	Subjects meeting all the following criteria will be included in the study: 1.Male & female (post-menopausal, surgically sterilized or practicing a reliable method of birth control during the duration of study) patients with age ranging from 18 to 65 years (both inclusive). 2.Having clinically confirmed diagnosis of chronic spontaneous urticaria characterized by erythematous skin wheals accompanied by itching attributable to no identifiable cause and occurring regularly at least three times per week for 6 weeks prior to entry in the study. 3.Having a symptom score of >2 (i.e, moderate-to-severe intensity scores) for any of two of the three features of pruritus, number of wheals, or maximum size of wheals (rated on pre-defined scales of 0 to 3) for at least 3 days during the screening visit (Day-7) and randomization visit (Day 1). 4.Subjects who are willing to sign informed consent for participation in the study and willing to adhere to all protocol procedures.

Exclusion Criteria

Exclusion Criteria	
Details	Subject will be excluded from the study for any of the following reasons: 1.Patients with a history of any dermatological condition (including isolated hereditary angioedema, dermographism, physical urticaria, urticaria caused by a medicine or food allergy, infectious urticaria, contact urticaria, urticaria caused by vasculitis and/or collagenosis, paraneoplastic urticaria, parasitary urticaria, urticaria related with thyroid pathology, eczema or atopic dermatitis), which could interfere in the evaluation of the chronic spontaneous urticaria. 2.Patients with a history of autoimmune disorders, Hodgkin's

	disease and any clinically signi?cant condition (cardiovascular, neurological, hepatic, renal or malignant diseases). 3.Patients who had taken systemic or topical corticosteroids within 4 weeks, astemizole within 6 weeks, ketotifen within 2 weeks, any other systemic antihistamine (including loratadine, desloratadine, ebastine, rupatadine, mizolastine, cetirizine or levocetrizine) within 3 days, anti-leukotrienes within 3 days, sodium cromoglycate or nedocromil within 2 weeks, and tricyclic antidepressants within 1 week of randomization. 4.Patients with hypersensitivity to H1-antihistamines, benzimidazoles or lactose. 5.Known hypersensitivity to the drug components (study drug or excipient) used during the study. 6.Pregnant or lactating women. 7.Subjects with evidence of skin conditions that would interfere with clinical assessments in the opinion of the investigator. 8.Subjects with active substance abuse or a history of substance abuse within 6 months prior to Screening. 9.Subjects with bacterial infections requiring treatment with oral or injectable antibiotics, or significant viral or fungal infections. 10.Subject who have used any investigational drug or device within 30 days of randomization preceding informed consent or scheduled to participate in another clinical study involving an investigational product or investigational drug during the course of this study. 11.Any observational finding (clinical evaluation / physical) that is interpreted by the investigator as a risk to the research participant's participation in the clinical trial. 12.Female participants who are in the reproductive age and do not agree to use acceptable methods of contraception (oral contraceptives, injectable contraceptives, intrauterine device (IUD), hormonal implants, barrier methods, hormonal patch and tubal ligation).

Method of Generating Random Sequence	Stratified block randomization
Method of Concealment	Other
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
To evaluate the efficacy of Bilastine 40mg when used for the treatment of chronic spontaneous urticaria.	Day -7, Day 1, Day 14, Day 28

Secondary Outcome

Outcome	Timepoints
To evaluate the safety of Bilastine 40mg when used for the treatment of chronic spontaneous urticaria.	Day -7, Day 1, Day 14, Day 28

Target Sample Size	**Total Sample Size=**200 **Sample Size from India=**200 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 3
Date of First Enrollment (India)	18/11/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	This is a Phase III, Multicentric, Comparative, Randomized, Double blind, Parallel group clinical study to evaluate the efficacy and safety of Bilastine Tablet 40mg once daily Vs. Bilastine Tablet 20mg Vs. Levocetrizine Tablet 10 mg once daily when used in treatment of subjects with chronic spontaneous urticaria. Male and female subjects between 18 to 65 years (both inclusive) with clinically confirmed diagnosis of chronic spontaneous urticaria characterized by erythematous skin wheals accompanied by itching attributable to no identifiable cause and occurring regularly at least three times per week for 6 weeks prior to entry in the study will be screened for eligibility to participate in the study. Eligible patients will be additionally required to demonstrate a symptom score of >2 (i.e, moderate-to-severe intensity scores) for any of two of the three features of pruritus, number of wheals, or maximum size of wheals (rated on pre-defined scales of 0 to 3) for at least 3 days during the screening visit (Day-7) and randomization visit (Day 1) will be enrolled for treatment and randomized in any of the treatment groups (Bilastine 40mg vs. Bilastine 20mg vs. Levocetrizine 10mg) in a 1:1:1 ratio. EVALUATION OF SAFETY: An adverse event is defined as any untoward medical occurrence (sign, symptom or laboratory finding), regardless of severity and whether or not attributed to the investigational product. All adverse events, whether observed by an Investigator or Study Coordinator or reported by the subject, whether related to study drug or not related to study drug, shall be documented on the CRF and subject records, together with details, i.e. date of onset, the duration and intensity of each episode, the action taken, the relationship to the investigational product and the degree of severity, the seriousness and the outcome. Safety and tolerability to treatment were evaluated according to routine laboratory tests (haematology and biochemistry), 12-lead ECGs, clinical examinations, and the incidence, severity and type of AEs reported by the patients over the course of treatment. All AEs were coded using the Medical Directory for Regulatory Activities (MedDRA) and grouped by treatment. The number and percentage of AEs, SAEs, AEs leading to discontinuation, and AEs related to study drug will be summarized by system organ class, preferred term and treatment group. The number and percentage of AEs by severity will also be summarized. All AEs will be displayed in listings. No inferential analyses are planned. Summary of vital signs, laboratory parameter values at relevant time points as well as change from baseline will be presented. Summary of physical examination findings will be presented by visit.

Summary of concomitant medications will be presented. Safety evaluations in the study will be performed using Safety Analysis Set (SAF). The Safety Analysis Set (SAF) consists of all subjects who took at least 1 dose of study medication, and will be used for safety analyses.

A descriptive analysis comparing the adverse events in both the treatment groups will be performed.

EVALUATION OF EFFICACY: The primary efficacy parameter will be:

Change from baseline in the patient?s reflective daily total symptoms score (TSS) over the 28-day treatment period, with baseline defined as the mean of the 3 days with maximum symptoms before randomization.

The secondary efficacy parameters include effect after 2-4 weeks treatment on:

? the change from randomization visit (Day 1) in the patients? and investigators mean instantaneous total and individual symptoms scores;

? the change from randomization visit (Day 1) in the patients? DLQI scores;

? the patients? VAS scores;

? the patients? impact of urticaria on sleep scores;

? the investigator?s GCI of treatment.

Test & Comparator Groups:

Test product (Arm 1): Bilastine Tablets 40mg

Comparator Product (Arm 2): Bilastine Tablets 20mg Comparator Product (Arm 3): Levocetrizine Tablets 10mg

SASTRA

Reg. No. ECR/324/indt/DL/2020

Society for Academic, Scientific & Translational Research Advancement (SASTRA) Ethics Committittee For Clinical Trials

Registered with Central Drugs Standards Control Organization, Ministry of Health & Family Welfare, Govt. of India

Letter No: SEC/ASZ/2021-001

Date: 31 Mar 2021

To,

Dr. Shivani Bansal,
Principal Investigator,
Prof. (Internal Medicine)
Santosh Medical College Hospital,
#1, Ambedkar Road, Ghaziabad,
Uttar Pradesh-201001

Reference: Your emails Dated-22 Mar 2021 and subsequent hard copy submission received by this office vide inward no. 09 on 23 Mar 2021 - reg.

Subject: Approval to conduct Phase II clinical trial at Santosh Medical College Hospital, Ghaziabad - regarding.

Dear Dr. Shivani Bansal,

The Society for Academic Scientific & Translational Research Advancement (SASTRA) Independent Ethics Committee reviewed and discussed your application to conduct the clinical trial entitled "**Protocol Title: A prospective, pilot, clinical trial to evaluate the efficacy and safety of COLchicine for improvement of clinical outcomes during COronaVirus (COVID-19) disease treatment in high-risk INdian patients.**" [Study Acronym: COLCOVIN] in the meeting of Ethics Committee held on 25th Mar. 2021.

The following documents were reviewed:

(a) Trial protocol ID: ICS/LAX/2021-001, Ver. No. 1.0, Date : 18 Jan 2021
(b) Patient information sheet and informed consent form in English language (version: 1.0 dated 18 Jan 2021).
(c) SmPC / Prescribing Information for Colchicine Tablets 0.5mg.
(d) Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.
(e) Principal investigator's current Curriculum Vitae.

Contd...

(f) Draft Clinical Trial Agreement

(g) Investigator's undertaking.

The following members of the ethics committee were present at the meeting held on 25th Mar. 2021 from 04:00 PM to 06:00 PM at EC Office located at Pitampura, Delhi and also via video conferencing.

1.	DR. CHAKRA DHAR TRIPATHI	Chairperson
2.	Ms. SHWETA SAHNI	Member Secretary
3.	DR. VIJAY KUMAR GARG	Clinician
4.	Dr. MEGHA VIJ	Basic Medical Scientist
5.	Mr. ALI SARDAR ZAIDI	Legal Expert
6.	Ms. ISHA THAKUR	Legal Expert
7.	Mr. NIRAJ SINGH YADAV	Member
8.	Dr. ASHISH RANJAN	Social Scientist
09.	Mr. SATISH KAPOOR	Social Scientist
10.	Ms. SHALINI SHEKHAR	Lay Person
11.	Ms. Bhanu Vij	Lay Person

We approve the trial to be conducted in its presented form.

Conditions of Approval:

1. Progress report of the study should be submitted Ethics Committee on quarterly basis.
2. Any Serious Adverse Events (SAE) occurring in the course of the study should be reported by the investigator to Ethics Committee within 24 hours of occurrence. In case of delay in reporting within stipulated period, reports of SAE alongwith reason for delay needs to be provided by the investigator alongwith the report of SAE.

Contd...

REGISTRAR

3. Any changes in the study protocol and patient information or informed consent to be submitted & approved by the Ethics Committee prior to implementation.
4. Copy of Final Study Report to be submitted to Ethics Committee.
5. **Translated and back translated version of approved Patient Information Sheet and Informed Consent Form in vernacular language to be submitted and approved from Ethics Committee prior to initiation of the study at the site.**
6. **Copy of valid Insurance policy Or Undertaking / Declaration for providing Compensation for participation and for serious adverse events occurring during the participation to be submitted prior to initiation of the study.**
7. **Informed consent should be obtained from every patient as per protocol before enrolment in the clinical trial. The informed consent should be administered in the vernacular language which is easily understood by the subject.**
8. **You should to intimate the Ethics Committee upon first enrollment at the Study site followed by routine updates on study progress and details of AE/ SAE if any during the study.**

Yours sincerely,

Shweta Sahni

DN: c=IN, o=Personal, title=9987, pseudonym=ec2f774ee76bcf39f9f450cef9a80fed5c3c3f2d, 2.5.4.20=a49473bf065a3741222929caebb4a210c1d7ba7e1cb2863e2a6966c3a4735c9b, postalCode=110085, st=Delhi, serialNumber=382bd2ac34e74bcc7c59adba72bbbf8b47d5307a606a4cf94db0085d3f22e778de, cn=Shweta Sahni
Date: 2021.03.31 18:43:19 +05'30'

Member Secretary,
SASTRA Ethics Committee

DEEMED TO BE UNIVERSITY
REGISTRAR
THANJAVUR

Clinical Trial Details (PDF Generation Date :- Tue, 28 Mar 2023 10:25:32 GMT)

CTRI Number	CTRI/2021/04/032555 [Registered on: 06/04/2021] - **Trial Registered Prospectively**
Last Modified On	26/10/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group Trial
Public Title of Study	A Clinical Trial to Assess the Efficacy, Safety and tolerability of Colchicine for Covid-19 Disease Treatment in Indian Patients.
Scientific Title of Study	A prospective, pilot, clinical trial to evaluate the efficacy and safety of Colchicine for improvement of clinical outcomes during Coronavirus (COVID-19) disease treatment in high-risk Indian patients.

Secondary IDs if Any

Secondary ID	Identifier
ICS/LAX/2021-001 Version 1.0 Dated 18 Jan 2021	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Details Contact Person (Scientific Query)

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Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India North West

	DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Laxai Life Sciences Pvt Ltd Third Floor, Ventureast Plaza, Plot # 40 & 41, Road No. 2, Financial District, Nanakramguda, Ranga Reddy District, Telangana 500032 India

Primary Sponsor

Primary Sponsor Details	
Name	Laxai Life Sciences Pvt Ltd
Address	Third Floor, Ventureast Plaza, Plot No. 40 and 41, Road No.2, Financial District, Nanakramguda, Ranga Reddy District, Telangana - 500032 India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
Council Of Scientific And Industrial ResearchIndian Institute Of Chemical Technology CSIRIICT	Uppal Rd, IICT Colony, Tarnaka, Hyderabad, Telangana 500007

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr R N Sechassayana	Aarupadai Veedu Medical College and Hospital	Ground Floor, Department of Paediatrics, Aarupadai Veedu Medical College and Hospital, Kirumampakkam, Puducherry- 607403 Pondicherry PONDICHERRY	914132615246 narayanassamyseshassayanan28@gmail.com
Dr B L Shashi Bhushan	Bangalore Medical College and Research Institute	Room No 50 B Block Department of Pulmonary Medicine Victoria Hospital Fort KR Road Bangalore KARNATAKA	080-26701150 ShashiBhushanBL@Yahoo.com
Dr Sushila Kataria	Medanta - The Medicity	Department of Internal Medicine Division Internal Medicine Room No 30 Sector - 38, Gurgaon, Haryana 122001 India Gurgaon HARYANA	0124-4141414 0124-4834111 Mukul.Manchanda@Medanta.org
Dr Aneesh Raj	Noorul Islam Institute of Medical Science (NIMS) and Research Foundation	Covid Care Center, Aush Block , NIMS Medicity, Aralummoodu P.O. Neyyattinkara, Trivandrum-695123 Thiruvananthapuram KERALA	04712222115 draneeshraj@gmail.com

Dr Pravin Nagulal Soni	PCMC PGI Yashwantrao Chavan Memorial Hospital	Room 01 Third Floor Department of Medicine PCMC PGI Yashwantrao Chavan Memorial Hospital Sant Tukaran Nagar Vallabhnagar Pimpri Pune Pune MAHARASHTRA	020-67332222 DrPravinSoni18@Gmail.com
Dr Vijaykumar Barge	RCSM Government Medical College and CPR Hospital	Room 01, Department of Medicine, Dasara Chowk, Bhausingji Road, Town Hall, Kolhapur 416012 Kolhapur MAHARASHTRA	0231-2644233 0231-2644233 DrVijayBarge12@Gmail.com
Dr Shivani Bansal	Santosh Medical College Hospital	Fifth Floor, Covid Ward, Santosh Medical College Hospital#1, Ambedkar Road Ghaziabad, UTTAR PRADESH Ghaziabad UTTAR PRADESH	0120-2741141 0120-2741141 smchgzb@gmail.com
Dr Vishal Gupta	SMS Medical College & Attached Hospital	Room # 04, PRT Wing, Dhanwantri Block, SMS Medical College & Attached Hospital Jaipur RAJASTHAN	0141-2518370 DrVishalGuptaMD@Rediffmail.com
Dr Changalva Premdeep	Vijaya Super Speciality Hospital	Ground Floor, Room No. 7 Department of Pulmonology, Vijaya Super Speciality Hospital, 16-II/41 A Raghava Cine Complex Road, Pogathota, Nellore,-524001 Nellore ANDHRA PRADESH	08612321828 dr.premdeep88@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee for Human Research	Submittted/Under Review	No Date Specified	No
Ethics Committee of Bangalore Medical College & Research Institute	Approved	18/06/2021	No
Ethics Committee SMS Medical College Jaipur	Approved	14/07/2021	No
Institutional Ethical Committee Vinayaka Missions Medical College	Approved	11/11/2021	No
Institutional Ethics Committee Vinayaka Missions Kirupananda	Approved	11/11/2021	No

Variyar Medical College and Hospitals			
Institutional Ethics Committee, Govt. Medical College Govt. General Hospital	Approved	23/06/2021	No
Institutional Human Ethical Committee Aarupadai Veedu Medical College and Hospital	Approved	11/11/2021	No
Medanta Institutional Ethics Committee	Approved	15/06/2021	No
NIMS IEC	Approved	12/10/2021	No
PGMCs PGI YCMH Ethics Committee	Approved	04/05/2021	No
Rajarshee Chhatarpati Shahu Maharaj Govt Medical College and Chhatarpati Pramila Raje Hospital, Kolhapur Institutional Ethics Committee 2	Approved	14/07/2021	No
Society for Academic, Scientific & Translational Research Advancement	Approved	31/03/2021	Yes
Vijaya Ethics Committee	Approved	17/01/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	05/02/2021

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere
Patients	Other specified respiratory disorders

Intervention / Comparator Agent

Type	Name	Details
Intervention	Colchicine 0.5mg tablets plus Standard of Care	Colchicine 0.5mg tablets plus Standard of Care Dose 0.5 mg, Frequency BID, Route of Administration Oral, Duration of Therapy 28 Days
Comparator Agent	Standard of Care	Standard of Care

Inclusion Criteria

Inclusion Criteria	
Age From	40.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	Subjects meeting all the following criteria will be included in the study: 1.Male & Female patients with age ranging from 40 to 65 years (both inclusive)& female (non-pregnant, non-lactating, post-menopausal, surgically sterilized or practicing a reliable method of birth control during the duration of study) 2.Clinically stable condition for at least 6 months before enrollment. 3.Confirmed diagnosis of at least moderate COVID-19 symptoms demonstrated by: a.Positivity in RT-PCR 2019-nCov test on

	respiratory tract (nasopharyngeal / oropharyngeal) specimens. b.Presence of clinical features of dyspnea and/or hypoxia, fever, cough, including SpO2 < 94% (range 90-94%) on room air, Respiratory Rate > 24 and < 30 breaths per minute. 4.Significant COVID-19 symptoms, and judged by the treating doctor to be at high risk of progression to severe category due to presence of any of the following: a.Having at least one of the high-risk criteria, i.e, obesity (BMI ? 30 kg/m2), diabetes mellitus, uncontrolled hypertension (diastolic blood pressure > 90 mm Hg systolic blood pressure ?150 mm Hg), known respiratory disease (including asthma or chronic obstructive pulmonary disease), known heart failure, known coronary disease; b.Demonstrating signs of cardiac injury due to Elevated troponin level, 5.Patients who require hospitalization for control of disease at the time of study entry. 6.Within 7 days from symptom onset or within 48 hours of laboratory diagnosis of SARS- CoV2. 7.Able to take oral tablets and agreeing not to participate in any other study for duration of participation in this study. 8.Willing to sign voluntary informed consent for participation in the study and willing to adhere to all protocol procedures. In case the subject is unable to provide informed consent than the same should be obtained from legally acceptable representative (LAR).

Exclusion Criteria

Exclusion Criteria	
Details	1.History of present illness (will be based on treating physician's opinion) a.Neurological and neurodevelopmental disorders. b.Congenital heart disease c.Severe heart disease or a history of clinically significant arrhythmias which may affect participants safety (According to the ECG or medical history). Corrected QT interval of 450 milliseconds or higher (according to the Bazett formula) on a 12 lead surface ECG / Abnormal ECG (to eliminate concerns that a potential interaction between colchicine and hydroxychloroquine could lead to excess QT prolongation) 2.Requirement of oxygen supplementation greater than 8L nasal cannula at the time of enrollment. 3.Treating physician clinical judgement that the patient will require mechanical respiratory support within 24 hours. 4. Patient currently in Septic shock or with hemodynamic instability requiring vasopressors. 5.History of cirrhosis. 6.A subject undergoing hemodialysis. 7.Severe gastrointestinal failure, severe gastrointestinal disorders, or stomach ulcer. 8.Patient is currently taking colchicine for other indications (gout or Familial Mediterranean Fever). 9.Patient with inflammatory bowel disease (Crohns disease or ulcerative colitis), chronic diarrhea or malabsorption 10.Severe Hepatic Insufficiency (ALT or AST greater than 5 times ULN) or Renal Failure (eGFR using the MDRD equation for all

	subjects less than 30 mL per min). 11.Patient received Remdesivir, Sarilumab, Tocilizumab, Lopinavir, Ritonavir or other immunomodulator given for COVID-19 treatment prior to study entry. 12.Patient is on (and cannot discontinue) a strong CYP3A4 inhibitor (e.g. clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, atazanavir), a moderate CYP3A4 inhibitor (e.g. diltiazem, verapamil, fluconazole, amprenavir, aprepitant, fosamprenavir) or a Pgp Inhibitor (e.g. cyclosporine, ranolazine). 13.Patients who may require IL 6 inhibitors as per clinical judgment of the investigator for management of inflammation at the time of study entry. 14. Pregnant or lactating women women of a childbearing age with a positive pregnancy test

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Time to clinical improvement of 2-points on WHO 8-point ordinal scale	28 days (4 weeks)

Secondary Outcome

Outcome	Timepoints
Improvement in cardiac & biochemical inflammatory markers	28 days
Time to discharge from hospital	28 days
Rate of viral clearance	28 days
Patients requiring auxiliary oxygen therapy (non-invasive/invasive) & time on auxiliary oxygen therapy.	28 days
All-cause mortality.	28 days
Adverse events (Serious, Expected/Unexpected, Related/Non-Related).	28 days

Target Sample Size	**Total Sample Size**=84 **Sample Size from India**=84 **Final Enrollment numbers achieved (Total)**=Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)**=Applicable only for Completed/Terminated trials
Phase of Trial	Phase 2
Date of First Enrollment (India)	07/04/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years**=0 **Months**=6 **Days**=0

Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	NIL
Brief Summary	

This is a Pilot Phase II, randomized, open label, prospective, comparative, two-arm, multi-center clinical study to evaluate the efficacy and safety of Colchicine for improvement of overall clinical outcomes when added to Standard of Care (SOC) treatment in high-risk Indian patients suffering with coronavirus (COVID-19) disease.

The proposed study is a two phase clinical study wherein first phase is Treatment Phase of 28 days followed by Follow-up Phase of 14 days. High risk patients with clinically confirmed & documented diagnosis of moderate coronavirus disease (COVID-19) as per MOH Criteria who require hospitalization for management of the disease, i.e.,

- Confirmed diagnosis of COVID-19 demonstrated by positivity in RT-PCR 2019-nCov test on respiratory tract (nasopharyngeal / oropharyngeal) specimens.
- Presence of clinical features of dyspnea and/or hypoxia, fever, cough, including SpO2 < 94% (range 90-94%) on room air, Respiratory Rate > 24 and < 30 breaths per minute
- Age above 40 to 65 years (both inclusive).
- Having at least one of the high-risk criteria, i.e, obesity (BMI ? 30 kg/m2), diabetes mellitus, uncontrolled hypertension (diastolic blood pressure > 90 mm Hg & systolic blood pressure ?150 mm Hg), known respiratory disease (including asthma or chronic obstructive pulmonary disease), known heart failure, known coronary disease.

will be screened and enrolled for participation in the study as per study protocol.

The treatment period with investigational product in test group will be 28 days from the day of first dose. It is however necessary that all patients in either test or control groups be allowed to take concomitant SOC as per the prescribed schedule for entire duration of the study, as applicable.

SASTRA

Reg. No. ECR/324/indt/DL/2020
Society for Academic, Scientific & Translational Research Advancement (SASTRA) Ethics Committee For Clinical Trials
Registered with Central Drugs Standards Control Organization, Ministry of Health & Family Welfare, Govt. of India

Letter No: SEC/ASZ/2021-010

Date: 25.11.2021

To,

Dr. Ashok Kumar,
(Professor & Head, Department of Medicine),
Santosh Medical College Hospital,
Ghaziabad.

Reference: Your submission Dated-19th Nov. 2021, received by this office vide inward no. 24 on 19th Nov, 2021.

Subject: Approval to conduct Phase IV clinical trial at Santosh Medical College Hospital, Ghaziabad, U.P. - regarding.

Dear Dr. Ashok Kumar,

The Society for Academic Scientific & Translational Research Advancement (SASTRA) Independent Ethics Committee reviewed and discussed your application to conduct the clinical trial entitled "**Protocol Title: AN OBSERVATIONAL, PRESCRIBER BASED, MULTICENTRIC, POST MARKETING SURVEILLANCE STUDY (PMS) TO GENERATE SAFETY & EFFICACY DATA OF FIXED DOSE COMBINATION (FDC) OF CODEINE PHOSPHATE 10mg & CHLORPHENIRAMINE MALEATE 4mg PER 5ml ORAL SYRUP FOR MANAGEMENT OF SYMPTOMS OF DRY COUGH IN ADULT PATIENTS**" in the meeting of Ethics Committee held on 20th Nov 2021.

The following documents were reviewed:

(a) Trial protocol ID: ICS/LAB/2021-004, Ver. No. 2.0, Date : 19 Oct 2021
(b) Patient information sheet and informed consent form in English language (version: 2.0 dated 19 Oct. 2021).
(c) SmPC / Prescribing Information for Codeine Phosphate 10mg & Chlorpheniramine Maleate 4mg per 5ml oral syrup.
(d) Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.

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(e) Principal investigator's current Curriculum Vitae.

(f) Draft Clinical Trial Agreement

(g) Undertaking from Sponsor for medical management for SAE and financial compensation in case of study related injury or death.

The following members of the ethics committee were present at the meeting held on 20th Nov. 2021 from 03:30 PM to 05:00 PM at EC Office (physical & virtually) located at Pitampura, Delhi and also via video conferencing.

01.	DR. CHAKRA DHAR TRIPATHI	Chairperson
02.	Ms. SHWETA SAHNI	Member Secretary
03.	DR. VIJAY KUMAR GARG	Clinician
05.	Dr. MEGHA VIJ	Basic Medical Scientist
06.	Mr. ALI SARDAR ZAIDI (Adv.)	Legal Expert
07	Ms. ISHA THAKUR (Adv.)	Legal Expert
07.	Mr. NIRAJ SINGH YADAV	Member
08.	Dr. ASHISH RANJAN	Social Scientist
09.	Mr. SATISH KAPOOR	Social Scientist
10.	Ms. SHALINI SHEKHAR	Lay Person
11.	Ms. Bhanu Vij	Lay Person

We approve the trial to be conducted in its presented form.

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Conditions of Approval:

1. The study should be notified to CDSCO and gets registered with registered prospectively at CTRI prior to enrollment of patients.
2. Any changes in the study protocol and patient information or informed consent to be submitted & approved by the Ethics Committee prior to implementation.
3. Copy of Final Study Report to be submitted to Ethics Committee.
4. **Informed consent should be obtained from every patient as per protocol before enrolment in the clinical trial. The informed consent should be administered in the vernacular language which is easily understood by the subject.**
5. **Copy of translated informed consent form along with Translation certificate to be submitted to Ethics Committee before study initiation as per protocol.**
6. **You should to intimate the Ethics Committee upon first enrollment at the Study site followed by routine updates on study progress and details of AE/ SAE if any during the study.**
7. **In case the study will enroll more than 100 patients at your site, same should intimated to EC before enrolling more than 100 patients.**

Yours sincerely,

Shweta Sahni

Digitally signed by Shweta Sahni
Date: 2021.11.25 15:42:53 +05'30'

Member Secretary,
SASTRA Ethics Committee

REGISTRAR

Clinical Trial Details (PDF Generation Date :- Tue, 28 Mar 2023 10:26:35 GMT)

CTRI Number	CTRI/2021/10/037217 [Registered on: 08/10/2021] - **Trial Registered Prospectively**
Last Modified On	22/04/2022
Post Graduate Thesis	No
Type of Trial	PMS
Type of Study	Drug
Study Design	Single Arm Study
Public Title of Study	A post marketing surveillance study to monitor the safety and efficacy of Codeine phosphate and Chlorpheniramine maleate for management of symptoms of dry cough in adult patients.
Scientific Title of Study	AN OBSERVATIONAL, PRESCRIBER BASED, MULTICENTRIC, POST MARKETING SURVEILLANCE STUDY (PMS) TO GENERATE SAFETY & EFFICACY DATA OF FIXED DOSE COMBINATION (FDC) OF CODEINE PHOSPHATE 10mg & CHLORPHENIRAMINE MALEATE 4mg PER 5ml ORAL SYRUP FOR MANAGEMENT OF SYMPTOMS OF DRY COUGH IN ADULT PATIENTS.

Secondary IDs if Any

Secondary ID	Identifier
ICS/LAB/2021-004 Version 2.0 Date 19 OCT 2021	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd., Room # 512, Clincal Trial Division, Clinical Operations Department , Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department , Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department , Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department , Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department , Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department , Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> LABORATE Pharmaceuticals India Limited, E-11 Industrial Area Panipat 132103 Haryana

Primary Sponsor

Primary Sponsor Details	
Name	LABORATE Pharmaceuticals India Limited
Address	E-11 Industrial Area Panipat 132103 Haryana
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
LABORATE Pharmaceuticals India Limited	E-11 Industrial Area Panipat 132103 Haryana

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr A Gopal Rao	Government Medical College and Government General Hospital (Old RIMSGGH)	Research Wing 2nd Floor Department of Medicine, Government Medical College and Government General Hospital (Old RIMSGGH), Srikakulam, Andhra Pradesh- 532001 Srikakulam ANDHRA PRADESH	9912320517 muralidhargudla@yahoo.com
Dr Ram Babu	Jaipur Golden Hospital	Room NO. 04, Clinical Trial Division, Medicine Dept., 02, Institutional Area, Sector III, Rohini, Delhi 110085 North West DELHI	011-27907000 011-27907000 JGHDSMO@GMAIL.COM
Dr Pathak Niranjan Pandurang	PCMCs PGI Yashwantrao Chavan Memorial Hospital	2nd Floor General Medicine Department PCMCs PGI Yashwantrao Chavan Memorial Hospital Sant Tukaram Nagar Pimpri Pune 411018	7057582759 drpratiksunservices@gmail.com

		Pune MAHARASHTRA	
Dr Ashok Kumar	Santosh Medical College & Hospital	3rd Floor, Clinical Trial Division, No 1, Ambedkar Road, Ghaziabad 201001 Ghaziabad UTTAR PRADESH	1204666650 smchgzb@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee Govt. Medical College Govt. General Hospital	Approved	31/01/2022	No
Institutional Ethics Committee-Yashwantrao Chavan Memorial Hospital	Approved	05/01/2022	No
Society for Academic Scientific Translational Research Advancement Ethics Committee	Approved	25/11/2021	Yes
Society for Academic Scientific Translational Research Advancement Ethics Committee	Approved	25/11/2021	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Other specified respiratory disorders

Intervention / Comparator Agent

Type	Name	Details
Intervention	Codeine Phosphate 10mg and Chlorpheniramine Maleate 4mg	Codeine Phosphate 10mg and Chlorpheniramine Maleate 4mg per 5 ml syrup two times daily for 7 days
Comparator Agent	NOT APPLICABLE	NOT APPLICABLE

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Male & female (non-pregnant, non-lactating, post-menopausal, surgically sterilized or practicing a reliable method of birth control during the duration of study) Subjects with age ranging from 18 to 65 years (both inclusive). 2. Subjects having dry cough (less than 7 days) of any origin and may be with related symptoms as Throat Pain, throat redness, Throat irritation/itching, (Fever if present) (absence of bronchial mucus/phlegm production). 3. Not under any antibacterial or antiviral treatment before recruitment. 4. Subjects ready to abstain from using any drug (which will affect the study outcome) other than Investigational Product for the treatment of the study condition during the study period (except in cases when patient's condition worsens as per study physician. In this case, Study physician will decide to prescribe antibiotic, if required). 5. Ready to abstain from the administration of any herbal or ayurvedic treatment

	or gargles directed to ease coughing or throat parameters. 6. Willing to provide written informed consent 7. Willing and able to understand and comply with all study requirements

Exclusion Criteria

Exclusion Criteria	
Details	1. Subjects with known allergy or hypersensitivity to Codeine Phosphate or Chlorpheniramine Maleate or any of its components. 2. Subjects who had taken any medicated confectionary, throat pastille, spray or any product with demulcent properties, any cough medicines or drugs containing antihistamines within last 24 hours prior to screening. 3. Subjects taking medications with known cough promoting side effects (e.g., angiotensin converting enzyme inhibitors or angiotensin II receptor blockers) that in the opinion of the investigator are causing symptoms of cough. 4. Subjects with diagnosis of diseases of pneumonia, asthma, sinusitis, allergic rhinitis, as well as heart disease. 5. Severe cough requiring hospitalization 6. Subjects who had used any local anesthetic within the past 24 hours. 7. Subjects who have used a longer acting or slow release analgesic during the previous 24 hours. 8. Maintenance therapy with any drug, or history of drug dependency, alcohol abuse, or serious neurological or psychological disease 9. Any other condition, which in the opinion of the clinician/investigator, could interfere significantly with the treatment and assessment process 10. Use of any investigational therapy within 30 days prior to randomization

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Adverse Events, Serious Adverse Events, Unexpected Adverse Events, Adverse Drug Reactions and Treatment Emergent Adverse Events.	7 Days

Secondary Outcome

Outcome	Timepoints
Change in the cough severity(daily) and frequency (daily) score assessed during follow-up visit at Day 3 and Day 7 or up to complete recovery (whichever is earlier) compared to the baseline.	Day 3 and Day 7
Number of awakenings in the night due to cough (24 hours) assessed during follow-up visit	Day 7
Time taken for complete cough relief (days) assessed during follow-up visit	Day 7
Change in score of throat pain and throat irritation	Day 7

Target Sample Size	**Total Sample Size=**200 **Sample Size from India=**200 **Final Enrollment numbers achieved (Total)=**0 **Final Enrollment numbers achieved (India)=**200
Phase of Trial	Post Marketing Surveillance
Date of First Enrollment (India)	15/10/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Not Applicable
Brief Summary	This is a prospective, single arm, multi-center, open-label, prescriber based, observational Post Market Surveillance study in Indian adult subjects who have symptoms of cough associated with upper respiratory allergies or common cold aged 18 years or older. The current study will aim to evaluate the safety and efficacy of fixed dose combination of Codeine Phosphate 10mg & Chlorpheniramine Maleate 4mg per 5ml oral syrup in the actual field conditions for the management of symptoms of cough associated with upper respiratory allergies or common cold. The duration of individual participation will be approximately 7 days (7 days treatment period). Key safety assessments include : Adverse Events (AEs), Serious Adverse Events (SAEs), Unexpected Adverse Events, Adverse Drug Reactions. Key efficacy assessments include : Change in the cough severity (daily) and frequency (daily) score assessed during follow-up visit at Day 3 and Day 7 or up to complete recovery (whichever is earlier) compared to the baseline, Number of awakenings in the night due to cough (24 hours) assessed during follow-up visit, Time taken for complete cough relief (days) assessed during follow-up visit, Change in score of throat pain and throat irritation.

Letter No: SEC/ASZ/2022-001

Date: 18.01.2022

To,

Dr. Ashok Kumar,
(Professor & Head, Department of Medicine),
Santosh Medical College Hospital,
Ghaziabad.

Reference: Your submission Dated 08th Jan. 2022, received by this office vides inward no. 29 on 08th Jan. 2022.

Subject: Approval to conduct Phase III clinical trial at Santosh Medical College Hospital, Ghaziabad, U.P. - regarding.

Dear Dr. Ashok Kumar,

The Society for Academic Scientific & Translational Research Advancement (SASTRA) Independent Ethics Committee reviewed and discussed your application to conduct the clinical trial entitled "**Protocol Title: A Multicenter, Randomized, Double-Blind, Parallel-Group, Comparative, Active-Controlled, Phase III Clinical Trial to evaluate the Efficacy and Safety of Fixed-Dose Combination of Bisoprolol 5 mg and Telmisartan 40 mg tablet versus Fixed-Dose Combination of Metoprolol Succinate ER 50 mg and Telmisartan 40 mg in Subjects with mild to moderate hypertension**" in the meeting of Ethics Committee held on 15th Jan. 2022.

The following documents were reviewed:

(a) Trial protocol ID: BITEL/WBL/P3/2021, Ver. No. 2.0, Date : 14 Oct 2021

(b) Patient information sheet and informed consent form in English language (version: 2.0 dated 14 Oct. 2021).

(c) Investigational Product Safety Information (Ver. No. 2.0, Date : 14 Oct 2021).

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(d) Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.

(e) Principal investigator's current Curriculum Vitae.

(f) Draft Clinical Trial Agreement

(g) Undertaking from Sponsor for medical management & compensation.

The following members of the ethics committee were present at the meeting held on 15th Jan. 2022 from 03:00 PM to 04:30 PM at EC Office (virtually) via video conferencing.

01.	DR. CHAKRA DHAR TRIPATHI	Chairperson
02.	DR. KIRAN CHHABRA	Clinician
03.	DR. VIJAY KUMAR GARG	Clinician
04.	Dr. MEGHA VIJ	Basic Medical Scientist
05.	Mr. ALI SARDAR ZAIDI (Adv.)	Legal Expert
06.	Ms. ISHA THAKUR (Adv.)	Legal Expert
07	Mr. NIRAJ SINGH YADAV	Member
07.	Dr. ASHISH RANJAN	Social Scientist
08.	Mr. SATISH KAPOOR	Social Scientist
09.	Ms. SHALINI SHEKHAR	Lay Person
10.	Ms. BHANU VIJ	Lay Person
11.	Ms. SHWETA SAHNI	Member Secretary

We approve the trial to be conducted in its presented form.

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Conditions of Approval:

1. The study should be notified to CDSCO and gets registered with registered prospectively at CTRI prior to enrollment of patients.
2. Any changes in the study protocol and patient information or informed consent to be submitted & approved by the Ethics Committee prior to implementation.
3. Copy of Final Study Report to be submitted to Ethics Committee.
4. **Informed consent should be obtained from every patient as per protocol before enrolment in the clinical trial. The informed consent should be administered in the vernacular language which is easily understood by the subject.**
5. **You should to intimate the Ethics Committee upon first enrollment at the Study site followed by routine updates on study progress and details of AE/ SAE if any during the study.**
6. **In case of any SAE, EC should be informed with 24 hours of occurrence.**
7. **Sponsor should obtain appropriate medical insurance for the study and copy of insurance to be notified to EC.**

Yours sincerely,

Shweta Sahni

Digitally signed by Shweta Sahni
Date: 2022.01.18 17:41:03 +05'30'

Member Secretary,
SASTRA Ethics Committee

REGISTRAR

Clinical Trial Details (PDF Generation Date :- Tue, 28 Mar 2023 10:29:03 GMT)

CTRI Number	CTRI/2022/01/039787 [Registered on: 28/01/2022] - **Trial Registered Prospectively**
Last Modified On	30/09/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A Clinical Trial to evaluate the efficacy and safety of Bisoprolol and Telmisartan Fixed Dose Combination Tablets for management of Hypertension.
Scientific Title of Study	A Multicenter, Randomized, Double-Blind, Parallel-Group, Comparative, Active-Controlled, Phase III Clinical Trial to evaluate the Efficacy and Safety of Fixed-Dose Combination of Bisoprolol 5 mg and Telmisartan 40 mg tablet versus Fixed-Dose Combination of Metoprolol Succinate ER 50 mg and Telmisartan 40mg in subjects with mild to moderate hypertension.

Secondary IDs if Any

Secondary ID	Identifier
BITEL/WBL/P3/2021 version 2.0 date 14.10.2021	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr R M Chhabra
Designation	Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr R M Chhabra
Designation	Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India
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Email	Chhabradrrm@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr R M Chhabra
Designation	Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash

	Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Windlas Biotech Limited 40/1, Mohabewala Industrial Area, Dehradun – 248 110 Uttarakhand, India

Primary Sponsor

Primary Sponsor Details	
Name	Windlas Biotech Limited
Address	40/1, Mohabewala Industrial Area, Dehradun – 248 110 Uttarakhand, India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
Windlas Biotech Limited	40/1, Mohabewala Industrial Area, Dehradun – 248 110 Uttarakhand, India

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Sudhir Kumar Bhatnagar	Abhinav Multispeciality Hospital	Room No 01 Department of Cardiology, Abhinav Multispeciality Hospital, Nayanakasha, Kamal Chowk, Nagpur, Maharashtra 440017 Nagpur MAHARASHTRA	9823148978 a_bawangade@yahoo.com
Dr A Gopal Rao	Govt. Medical College and Govt. General Hospital	Dept. of Medicine, Govt. Medical College & Govt. General Hospital(Old RIMSGGH), Srikakulam 532001 Srikakulam ANDHRA PRADESH	9912320517 muralidhargudla@yahoo.com
Dr Giriraja K V	Rajalakshmi Hospital and Research Center	Room No 01, Ground Floor, Department of General Medicine, Rajalakshmi Hospital and Research Center 21/1 Lakshmipura Main Road, Vidyaranyapura Post Bangalore KARNATAKA	08023254855 drgirirajkv@gmail.com
Dr Tanmoy Majee	Ruby General Hospital Ltd	Department of Clinical Pharmacology and Research, Ruby General Hospital Ltd, 576 Anandpur EM	03366011800 drtanmoymajee@gmail.com

		Bypass, Kasba, Kolkata Kolkata WEST BENGAL	
Dr Bal Kishan Gupta	S P Medical College and AG Hospitals	Department of Medicine S P Medical College and A G Hospitals Bikaner Rajasthan 334001 Bikaner RAJASTHAN	7615914143 manojbkn108@gmail.com
Dr Laxmi Kant Goyal	S.M.S. Medical College and Attached Hospitals	Ground Floor, Department of Medicine S.M.S. Medical College and Attached Hospitals JLN Marg Jaipur Rajasthan- 302004 Jaipur RAJASTHAN	09462651019 drlkgoyal@gmail.com
Dr Ashok Kumar	Santosh Medical College & Hospital	3rd Floor, Clinical Trial Division, No 1, Ambedkar Road, Ghaziabad 201001 Ghaziabad UTTAR PRADESH Ghaziabad UTTAR PRADESH	1204666650 smchgzb@gmail.com
Dr R M Chhabra	Saroj Super Speciality Hospital	Department of Internal Medicine, Saroj Super Speciality Hospital, Bhagawan Mahavir Marg, Near Madhuban Chowk, Block A, Sector 14, Rohini 110085 New Delhi DELHI	9147903333 drchhabrarm@yahoo.co.in
Dr Suhas N Kalashetti	Shree Samarth Hospital	Room No. 12 Department of Clinical Research Shree Samarth Hospital 227, Karande Chowk Pune, 411011 Pune MAHARASHTRA	02026128345 skalashetti@yahoo.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee S.M.S. Medical College and Attached Hospitals	Approved	27/04/2022	No
Ethics Committee, SP Medical College	Approved	25/02/2022	No
Institutional Ethics Committee Government Medical College and Government General Hospital	Approved	31/01/2022	No
Institutional Ethics Committee Ruby General Hospital	Approved	28/03/2022	No

Institutional Ethics Committee Shree Samarth Hospital	Approved	16/04/2022	No
Jasleen Hospital Ethics Committee	Approved	21/02/2022	No
Rajalakshmi Hospital Institutional Ethics Committee	Approved	15/03/2022	No
Society for Academic Scientific Translational Research Advancement Ethics Committee	Approved	18/01/2022	Yes
Society for Academic Scientific Translational Research Advancement Ethics Committee	Approved	08/02/2022	Yes

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	15/11/2021

Health Condition / Problems Studied

Health Type	Condition
Patients	Essential (primary) hypertension

Intervention / Comparator Agent

Type	Name	Details
Intervention	Fixed-Dose Combination of Bisoprolol 5 mg and Telmisartan 40 mg tablet	One tablet daily for 84 days
Comparator Agent	Fixed-Dose Combination of Metoprolol Succinate ER 50 mg and Telmisartan 40 mg tablet	One tablet daily for 84 days

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Male or female participants with age 18 years to 60 years (both inclusive) at the time of screening 2. Adult subjects who are capable of understanding and giving written informed consent and willing to comply with the study protocol 3. Subjects diagnosed with mild to moderate Essential Hypertension with SBP ranging between 140-159 mmHg and/or DBP ranging between 90-99mmHg 4. Females of non-child bearing potential (surgically sterile or menopausal) OR females of child bearing potential using effective birth control measures and non-pregnant & non-lactating females.

Exclusion Criteria

Exclusion Criteria	
Details	1. Subjects previously sensitive to any of the ingredients of the fixed-dose combination under study or beta-blockers or angiotensin receptor blockers, 2. Subjects with clinically significant renal (estimated glomerular filtration rate: 114 mm Hg) 5. Subjects with evidence of any cardiac arrhythmia on ECG 6. Any known cardiac disease/disorder in which any of the study medication is contra-indicated (e.g. severe bradycardia, heart block greater than a first degree or significant first-degree block, cardiogenic shock,decompensated cardiac failure, sick sinus syndrome without pacemaker etc.) 7. Subjects with known significant

	respiratory/liver/kidney/neurological diseases / uncontrolled diabetes, 8. Pregnant and lactating women or the women of child bearing age who are not practising the effective means of contraception, 9. Subjects otherwise judged to be inappropriate for inclusion in the study by the investigator's judgment 10. Subjects who will receive some other drug during the study besides that in the protocol that could alter the pharmacokinetic/ pharmacodynamic profile of the study drug, 11. Subjects with known alcohol or drug abuse 12. Subjects with known history of HIV, Hepatitis B and Hepatitis C
Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
Percentage of the subjects achieved the target levels of clinical BP among mild to moderate hypertensive subjects (target level: SBP less than 140 mm Hg and DBP less than 90 mm Hg)	12 weeks

Secondary Outcome

Outcome	Timepoints
Mean reduction in systolic and diastolic blood pressure measured in sitting position compared to baseline	4, 8 and 12 weeks
Proportion of responders after 12 weeks of dosing (Responder rate defined as the proportion of subjects with a decrease in diastolic BP by at least 10 mmHg).	12 weeks
Reduction in mean heart rate compared to baseline	4, 8 and 12 weeks
Adverse Events assessment, Physical and systemic examination, Vital signs, Lab abnormalities	4, 8 and 12 weeks

Target Sample Size	**Total Sample Size=**264 **Sample Size from India=**264 **Final Enrollment numbers achieved (Total)=**292 **Final Enrollment numbers achieved (India)=**292
Phase of Trial	Phase 3
Date of First Enrollment (India)	29/01/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**9 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	In India, Bisoprolol and Telmisartan are already approved and marketed. Therefore, considering the unmet need for an FDC and based on regulatory requirement M/s. Windlas Biotech Ltd. proposes the present study be conducted to generate data on the Indian population.The study design is a multi-centre study to evaluate efficacy and safety of fixed-dose combination (FDC) of Bisoprolol 5 mg and

Telmisartan 40 mg tablet in subjects with mild to moderate hypertension. The purpose of the presen t study is to demonstrate that a fixed-dose combination (FDC) of Bisoprolol 5 mg and Telmisartan 40 mg tablet is efficacious and safe in Indian subjects with regard to the routine clinical setting.

This will be a multicentre, randomized, double-blind, parallel-Group, comparative active-controlled phase III clinical trial to evaluate the efficacy and safety of fixed-Dose Combination of Bisoprolol 5 m g and Telmisartan 40 mg tablet versus a fixed-Dose combination of Metoprolol Succinate ER 50 mg and Telmisartan 40 mg tablets in subjects with mild to moderate hypertension. Initially, subjects will be screened as per predefined eligibility criteria for the study. The ITT population will include approximately a total number of 264 e ligible male and female patients of any ethnicity diagnosed with mild to moderate hypertension. Eligible 264 subjects will be either enrolled to receive Fixed-Dose Combination (FDC) of Bisoprolol 5 mg and Telmisartan 40 mg tablet or Fixed-Dose Combination of Metoprolol Succinate ER 50 mg and Telmisartan 40 mg tablets in 1:1 ratio.

Test
Arm: Treatment Arm 1: Fixed-Dose Combination (FDC) of Bisoprolol 5 mg and Telmisartan 40 mg tablet (n=132)

Reference Arm: Treatment Arm 2: Fixed-Dose Combination of Metoprolol Succinate ER 50 mg and Telmisartan 40 mg (n=132)

Efficacy:

Primary endpoint

- Percentage of the subjects achieved the target levels of clinical BP among mild to moderate hypertensive subjects (target level: SBP < 140 mm Hg and DBP < 90 mm Hg);

Secondary end point

- Mean reduction in systolic and diastolic blood pressure measured in sitting position compared to baseline (After 4, 8 and 12 weeks)
- Proportion of responders after 12 weeks of dosing (Responder rate defined as the proportion of subjects with a decrease in diastolic BP by at least 10 mmHg).
- Reduction in mean heart rate compared to baseline (After 4, 8 and 12 weeks)

Safety (Screening visit to end of study visit)

- Adverse Events (AE) assessment
- Physical & systemic examination
- Vital signs
- Lab abnormalities

Letter No: SEC/ASZ/2022-005

Date: 28.01.2022

To,
Dr. Ashok Kumar,
(Professor & Head, Department of Medicine),
Santosh Medical College Hospital,
Ghaziabad.

Reference: Your submission Dated 15th Jan. 2022, received by this office vides inward no. 32 on 15th Jan. 2022.

Subject: Correction in Approval letter dated 20 Jan 2022 - regarding.

Dear Dr. Ashok Kumar,

Please refer to this office letter no. SEC/ASZ/2022-003 dated 20 Jan 2022 regarding change in investigator for the study title "**Protocol Title: A multi-centric, phase-II, randomized, open label clinical study to evaluate efficacy, safety and tolerability of NIclosamide for the treatment of hospitalized COrona VIrus Disease (Covid-19) patients.**" Protocol No.: ICS/LAX/2020-006, Ver. No. 3.0, Date: 28 Mar 2021.

The subject line of aforementioned letter dated 20 Jan 2022 to read as **"Change of Investigator in Phase II clinical trial (Protocol No.: ICS/LAX/2020-006) - regarding."** all other conditions of the original approval letter reference number SEC/ASZ/2021-003 dated 20 May 2021 remains same.

Yours sincerely,

Shweta Sahni
Digitally signed by Shweta Sahni
Date: 2022.01.28 13:05:50 +05'30'

Member Secretary,
SASTRA Ethics Committee

SANTOSH DEEMED TO BE UNIVERSITY REGISTRAR GHAZIABAD, NCR DELHI

Letter No: SEC/ASZ/2021-003

Date: 20 May 2021

To,
Dr. (Prof.) Sanjay Sahay,
Professor and Head
Department of Pulmonary Medicine
Santosh Medical College & Hospital,
Ghaziabad (U.P.)

Reference: Your email Dated- 27thApril 2021, received by this office vide inward no. 12 on 27th April, 2021.

Subject: Approval to conduct Phase II clinical trial at Santosh Medical College Hospital, Ghaziabad. - regarding.

Dear Dr. (Prof.) Sanjay Sahay,

The Society for Academic Scientific & Translational Research Advancement (SASTRA) Independent Ethics Committee reviewed and discussed your application to conduct the clinical trial entitled "**Protocol Title: A multi-centric, phase-II, randomized, open-label clinical study to evaluate the efficacy, safety and tolerability of NIclosamide for the treatment of hospitalized COronaVIrus Disease (Covid-19) patients.**" [Study Acronym: NICOVID] in the meeting of Ethics Committee held on 13th May 2021.

The following documents were reviewed:

(a) Trial protocol ID: ICS/LAX/2020-006, Ver. No. 3.0, Date :28 Mar 2021.
(b) Patient information sheet and informed consent form in English (version: Ver. No. 3.0, Date : 28 Mar 2021) and Hindi (Version Ver. No. 3.0, Date : 28 Mar 2021) language.
(c) Proposed methods for patient accrual and their consent
(d) Principal investigator's current Curriculum Vitae.
(e) Investigator's undertaking.

SANTOSH DEEMED TO BE UNIVERSITY REGISTRAR GHAZIABAD, NCR DELHI

Contd…

(f) Draft Clinical Trial Agreement

(g) Undertaking from Sponsor for medical management for SAE and financial compensation in case of study related injury or death.

The following members of the ethics committee were present at the meeting held on 13th May. 2021 from 04:00 PM to 06:00 PM at EC Office located at Pitampura, Delhi and also via video conferencing.

01.	DR. CHAKRA DHAR TRIPATHI	Chairperson
02.	Ms. SHWETA SAHNI	Member Secretary
03.	DR. VIJAY KUMAR GARG	Clinician
04.	Dr. KIRAN CHABRA	Clinician
05.	Dr. MEGHA VIJ	Basic Medical Scientist
06.	Mr. ALI SARDAR ZAIDI	Legal Expert
07.	Mr. NIRAJ SINGH YADAV	Member
08.	Dr. ASHISH RANJAN	Social Scientist
09.	Mr. SATISH KAPOOR	Social Scientist
10.	Ms. SHALINI SHEKHAR	Lay Person
11.	Ms. Bhanu Vij	Lay Person

We approve the trial to be conducted in its presented form.

REGISTRAR

Conditions of Approval:

1. Progress report of the study should be submitted Ethics Committee on quarterly basis.
2. Any Serious Adverse Events (SAE) occurring in the course of the study should be reported by the investigator to Ethics Committee within 24 hours of occurrence. In case of delay in reporting within stipulated period, reports of SAE alongwith reason for delay needs to be provided by the investigator alongwith the report of SAE.

Contd…

3. Any changes in the study protocol and patient information or informed consent to be submitted & approved by the Ethics Committee prior to implementation.
4. Copy of Final Study Report to be submitted to Ethics Committee.
5. **Copy of valid Insurance policy for providing Compensation for participation and for serious adverse events occurring during the participation to be submitted prior to initiation of the study.**
6. **Informed consent should be obtained from every patient as per protocol before enrolment in the clinical trial. The informed consent should be administered in the vernacular language which is easily understood by the subject.**
7. **You should to intimate the Ethics Committee upon first enrollment at the Study site followed by routine updates on study progress and details of AE/ SAE if any during the study.**

Yours sincerely,

Shweta Sahni

Digitally signed by Shweta Sahni
DN: c=IN, o=Personal, title=9987, pseudonym=ec2f774ea76bcf59f9f450cef9a80fed5c3c3f2d, 2.5.4.20=a49473bf065a3741222929caebb4e210c1d7ba7e1cb2863e2a6966c3a4735c9b, postalCode=110065, st=Delhi, serialNumber=362bd2ac34e74bcc7c59adba72bb90b47d5307a60ea6cf64db085d3f22e778de, cn=Shweta Sahni
Date: 2021.05.20 19:36:55 +05'30'

Member Secretary,
SASTRA Ethics Committee

Clinical Trial Details (PDF Generation Date :- Tue, 28 Mar 2023 10:26:03 GMT)

CTRI Number	CTRI/2021/05/033791 [Registered on: 25/05/2021] - **Trial Registered Prospectively**
Last Modified On	26/04/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A Clinical Trial Evaluating Niclosamide for the Treatment of Covid-19 Disease.
Scientific Title of Study	A Multicentric Phase II Randomized Open Label Clinical Study to Evaluate Efficacy Safety and Tolerability of Niclosamide for the Treatment of Hospitalized Corona Virus Disease (COVID-19) Patients

Secondary IDs if Any

Secondary ID	Identifier
ICS/LAX/2020-006 Version 3.0 Dated 28 Mar 2021	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West Delhi, India Not Applicable North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West Delhi, India Not Applicable North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr R M Chhabra
Designation	Medical Monitor/Trial Coordinator
Affiliation	Insignia Clinical Services Pvt. Ltd.
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West Delhi, India Not Applicable North West

	DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Laxai Life Sciences Pvt. Ltd. Third Floor, Ventureast Plaza, Plot # 40 & 41, Road No. 02, Financial District, Nanakramguda, Ranga Reddy District, Telangana 500032 India

Primary Sponsor

Primary Sponsor Details	
Name	Laxai Life Sciences Pvt Ltd
Address	Third Floor, Ventureast Plaza, Plot # 40 & 41, Road No. 02, Financial District, Nanakramguda, Ranga Reddy District, Telangana 500032 India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
Council Of Scientific And Industrial Research Indian Institute Of Chemical Technology CSIRIICT	Uppal Road, IICT Colony, Tamaka, Hyderabad, Telangana 500007

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr A Thumjaa	Aarupadai Veedu Medical College and Hospital	Ground Floor, Department of Paediatrics, Aarupadai Veedu Medical College and Hospital, Kirumampakkam, Puducherry- 607403 Pondicherry PONDICHERRY	914132615246 thumjaa@gmail.com
Dr B L Shashi Bhushan	Bangalore Medical College and Research Institute	Room No 50 B Block Department of Pulmonary Medicine Victoria Hospital Fort KR Road Bangalore KARNATAKA	080-26701150 ShashiBhushanBL@Yahoo.com
Dr Aneesh Raj	Noorul Islam Institute of Medical Science (NIMS) and Research Foundation	Covid Care Center, Aush Block , NIMS Medicity, Aralummoodu P.O. Neyyattinkara, Trivandrum, Kerala-695123 Thiruvananthapuram KERALA	04712222115 draneeshraj@gmail.com
Dr Pravin Soni	PCMCs PGI Yashwant Rao Chavan Memorial Hospital	Covid Blocks 64A Ground Floor and 111 First Floor PCMCs PGI Yashwant Rao Chavan Memorial Hospital Sant Tukaram Nagar, Pimpri, Pune 411018 Pune	020-67332200 020-67332200 DrPravinSoni18@Gmail.com

		MAHARASHTRA	
Dr Vijaykumar Barge	RCSM Government Medical College and CPR Hospital	Room 01, Department of Medicine, Dasara Chowk, Bhausingji Road, Town Hall, Kolhapur 416012 Kolhapur MAHARASHTRA	0231-2644233 0231-2644233 DrVijayBarge12@Gmail.com
Dr Ashok Kumar	Santosh Medical College Hospital	First Floor, Department of General Medicine, Santosh Medical College Hospital #1, Ambedkar Road Ghaziabad, UTTAR PRADESH Ghaziabad UTTAR PRADESH Ghaziabad UTTAR PRADESH	0120-2741141 0120-2741141 SMCHGZB@Gmail.com
Dr Vishal Gupta	SMS Medical College & Attached Hospital	Room # 04, PRT Wing, Dhanwantri Block, SMS Medical College & Attached Hospital Jaipur RAJASTHAN	020-67332222 DrVishalGuptaMD@Rediffmail.com
Dr Changalva Premdeep	Vijaya Super Speciality Hospital	Ground Floor, Room No. 7 Department of Pulmonology, Vijaya Super Speciality Hospital, 16-II/41 A Raghava Cine Complex Road, Pogathota, Nellore, Andhra Pradesh-524001, India Nellore ANDHRA PRADESH	08612321828 dr.premdeep88@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee of Bangalore Medical College & Research Institute	Approved	18/06/2021	No
Ethics Committee SMS Medical College Jaipur	Approved	14/07/2021	No
Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital, Pimpri, Pune, Maharashtra	Approved	14/07/2021	No
Institutional Human Ethical Committee Aarupadai Veedu Medical College and Hospital	Approved	11/11/2021	No
NIMS IEC	Approved	12/10/2021	No
Rajarshee Chhatarpati Shahu Maharaj Govt Medical College and	Approved	14/07/2021	No

Chhatarpati Pramila Raje Hospital, Kolhapur Institutional Ethics Committee 2			
Society for Academic, Scientific & Translational Research Advancement	Approved	20/05/2021	Yes
Society for Academic, Scientific & Translational Research Advancement	Approved	20/05/2021	Yes
Vijaya Ethics Committee	Approved	17/01/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	20/04/2021

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere
Patients	Other specified respiratory disorders

Intervention / Comparator Agent

Type	Name	Details
Intervention	Niclosamide 2000 mg orally Plus Standard of Care	Niclosamide 2000 mg orally Plus Standard of Care Treatment Duration for 07 Days
Comparator Agent	Standard Of Care	Standard Of Care

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	Male & female (non-pregnant, non-lactating, post-menopausal, surgically sterilized, or practicing a reliable method of birth control during the duration of the study) patients with ages ranging from 18 to 65 years (both inclusive). Clinically stable condition for at least 6 months before enrollment. Confirmed diagnosis of moderate COVID-19 symptoms demonstrated by: Positivity in RT-PCR 2019-nCov test on respiratory tract (nasopharyngeal / oropharyngeal) specimens. Presence of dyspnea and/or hypoxia, fever, cough, including SpO2 < 93% (range 90-93%) on room air, Respiratory Rate > 24 and < 30 breaths per minute. Patients with SpO2 < 90% to be excluded from the study. Signs of pneumonia (lung injury/lung involvement) confirmed by Chest X-Ray at the time of study entry. Disease severity score between Grade 4 to 5 on the WHO 9-point ordinal scale & patient requires hospitalization for management of the disease. Within 7 days from symptom onset or within 72 hours of laboratory diagnosis of SARS-CoV2 via RT-PCR test. Able to take oral tablets at the time of study entry and agree not to participate in any other study for duration of participation in this study. Willing to sign voluntary informed consent for participation in the study and willing to adhere to all protocol procedures. In case the subject is unable to provide informed consent then the same should be obtained from a legally acceptable representative (LAR).

Exclusion Criteria

Exclusion Criteria	
Details	Subjects will be excluded from the study for any of the following

reasons:

Subjects with known allergy or hypersensitivity to Niclosamide or any of its components.

Patients who have previously had a disease severity score of 6 or 7 on the WHO 9-point ordinal scale.

Evidence of severe or critical illness, defined by at least 1 of the following:

Respiratory failure requiring at least 1 of the following:

Endotracheal intubation and mechanical ventilation, oxygen delivered by high flow nasal cannula

Extracorporeal membrane oxygenation (ECMO) or clinical diagnosis of respiratory failure

Shock (defined by systolic blood pressure (BP) 5times ULN].

Subjects with oxygen saturation (SpO2) ?90%.

Respiration Rate ?30 breaths per minute at the time of enrolment.

History of refractory nausea, vomiting, or chronic gastrointestinal disorders, inability to swallow the study drug, or having undergone extensive bowel resection which may affect adequate absorption of study medications.

Inability to swallow tablets (administration via nasogastric tube is permitted in patients who become unable to swallow after starting the study drug).

Patients who require IL-6 inhibitors for management of inflammation at the time of study entry.

Female subjects who are pregnant or involved in breastfeeding.

Subject was using adrenocorticosteroids (except topical or inhaled preparations) or immunosuppressive or immunomodulatory drugs (e.g., immunosuppressants, anticancer drugs, interleukins, interleukin antagonists, or interleukin receptor blockers) within one week prior to study entry.

Subject has a serious chronic disease (e.g., human immunodeficiency virus (HIV), hepatitis B virus or hepatitis C virus, cancer requiring chemotherapy within the preceding 6 months, unstable cardiac, pulmonary, neurologic, vascular, or endocrinologic disease states requiring medication dose adjustments within the last 30 days.

Has a history of alcohol or drug abuse in the previous 6 months.

Subject has a psychiatric disease that is not well controlled where controlled is defined as stable on a regimen for more than one year.

Subject already treated with another COVID 19 therapy but has relapsed with a positive diagnosis.

Hospital discharge is anticipated in ?24 hours.

	Anticipated transfer to another hospital which is not a study site within 72 hours. Participated in any other clinical trial or taken an investigational drug within 1 month.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Time to Clinical Improvement of 2-points on WHO 8-Point Ordinal Scale	Baseline, Day 03, Day 05, Day 07, Day 14, Day 21

Secondary Outcome

Outcome	Timepoints
Secondary outcome measures for this study will include: Time to respiratory viral clearance Improvement in lung injury on Chest X-Ray Other outcome measures for this study will include: All-cause mortality	Time frame : 3, 7, 10, 14 days Time frame: Baseline, 14, 21 days Time frame: 21 days

Target Sample Size	**Total Sample Size**=96 **Sample Size from India**=96 **Final Enrollment numbers achieved (Total)**=Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)**=Applicable only for Completed/Terminated trials
Phase of Trial	Phase 2
Date of First Enrollment (India)	01/06/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years**=0 **Months**=6 **Days**=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	NIL
Brief Summary	This is a Phase II, Randomized, Multi-centric, Open Label clinical study to evaluate the efficacy, safety & tolerability of Niclosamide when used alongside Standard of Care (SOC) for the treatment of hospitalized patients with coronavirus disease (COVID-19). The proposed study is a two phase clinical study wherein first phase, i.e, Treatment Phase will began when either a male or female (non-pregnant, non-lactating) patients between 18 to 65 years (both inclusive) with clinically confirmed & documented diagnosis of moderate coronavirus disease (COVID-19) with severity rating of Grade 4 or Grade 5 at the time of study entry as per WHO ordinal score and who require hospitalization for management of the disease will be screened and enrolled for participation in the study as per study protocol.

The treatment period with investigational product in test group will be 7 days. It is however necessary that all patients in either test or control groups be allowed to take concomitant SOC as per the prescribed schedule for entire duration of the study, as applicable. Follow-up Phase shall begin from EOT (Day 8) and will continue for another 2 weeks for each patient. During Follow-up Phase, all patients in both test and/or control groups will take SOC as advised per individual treatment plan and will be asked to monitor signs & symptoms of disease, status of clinical recovery and adverse events, if any.