Clinical Trial Details (PDF Generation Date :- Tue, 31 Jan 2023 05:30:32 GMT)

CTRI Number	CTRI/2021/05/033817 [Registered on: 27/05/2021] - **Trial Registered Prospectively**
Last Modified On	25/05/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Use of Steroid inhalers in COVID.
Scientific Title of Study	“Treating COVID-19 infection with inhaled corticosteroids

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

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

Details of Principal Investigator	
Name	Dr Raja Dhar
Designation	Consultant Pulmonologist
Affiliation	
Address	CK Birla Hospitals The Calcutta Medical Research Institute 7/2 Diamond Harbour Road,Kolkata Kolkata WEST BENGAL 700027 India
Phone	
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Email	pulmoresearch@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Raja Dhar
Designation	Consultant Pulmonologist
Affiliation	
Address	CK Birla Hospitals Pulmonology speciality clinic, Level 1 The Calcutta Medical Research Institute 7/2 Diamond Harbour Road,Kolkata Kolkata WEST BENGAL 700027 India
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Source of Monetary or Material Support

Source of Monetary or Material Support
> You Breathe We care, P-171/1 CIT Scheme VII-M, Kolkata-700054, West Bengal

Primary Sponsor

Primary Sponsor Details	
Name	YOU BREATHE WE CARE
Address	P-171/1 CIT Scheme VII-M Kolkata-700054,West Bengal
Type of Sponsor	Other [Not for profit research trust]

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 Raja Dhar	C.K.Birla Hospitals	Pulmonology specialty clinic, Level 1 The Calcutta Medical Research Institute 7/2 Diamond Harbour Road,Kolkata-700027. Kolkata WEST BENGAL	9831855512 pulmoresearch@gmail.com
Dr Rajesh Swarnakar	Get Well Hospital And Research institute	Deapartment of Respiratory, Critical Care, Sleep Medicine and Interventional Pulmonology Unit ground Floor, Room No- G3 20/1 Khare Marg, Dhantoli, Nagpur MAHARASHTRA	9822225130 drrajeshswarnakar@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee, The Calcutta Medical Research Institute	Approved	12/04/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Other specified viral diseases

Intervention / Comparator Agent

Type	Name	Details
Intervention	Budesonide dry powder inhaler	400 mcg budesonide inhaler. Two puffs twice a day up to twenty eight days
Comparator Agent	Usual care	Care of COVID-19 as per local guidelines

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)

Age To	99.00 Year(s)
Gender	Both
Details	1.Participant is willing and able to give informed consent 2.Male or Female aged 18 years or above 3.New onset of symptoms suggestive of COVID19 like new onset cough fever, loss of smell or taste within 7 or fewer days of participant being seen at visit 1 4.Able and willing to comply with all trial requirements as per Investigator

Exclusion Criteria

Exclusion Criteria	
Details	1.A known allergy to IMP 2. Any known contraindication to IMP 3. Patient currently prescribed inhaled or systemic corticosteroids 4.Recent use, within the previous 7 days of inhaled or systemic corticosteroids 5. Patient needs hospitalisation at time of study consent 6. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial. 7. Participants who have participated in another research trial involving an investigational product in the past 12 weeks

Method of Generating Random Sequence	Stratified block randomization
Method of Concealment	Centralized
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Hospitalisation or emergency department attendance related to COVID	Day zero to day twenty eight

Secondary Outcome

Outcome	Timepoints
Body temperature	Day zero to day twenty eight
Blood oxygen saturation level	Day zero to day twenty eight
Common cold questionnaire	Day zero to day twenty eight
FluPRO questionnaire	Day zero to day twenty eight
Nasal /throat swab	Day 0, Day 7-9

Target Sample Size	**Total Sample Size=**820 **Sample Size from India=**820 **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/ Phase 3
Date of First Enrollment (India)	30/05/2021
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)	Not Yet Recruiting
Publication Details	Not yet published

Brief Summary

This study is a randomised open label parallel group clinical trial.

The main objective is to evaluate the efficacy of Inhaled corticosteroid (ICS) therapy to standard care in participants with early COVID-19 illness. It also evaluate the effect of ICS therapy on physiology, symptoms, and viral load, compared to standard care in participants with early CoVID-19 illness.

Adult participants ?18 years with recent onset of symptoms suggestive of possible COVID-19 illness will be recruited from the community and primary care. Following confirmation of eligibility and consent participants will be recruited and randomly allocated to the interventional or standard of care arm of the study at a 1: 1 ratio. Participants randomised to the interventional arm will take ICS inhaler Budesonide via dry powder inhaler 1600mcg daily. Participants randomised to the standard care arm will receive study visits but will not receive any additional intervention.

The study includes four (4) visits; out of which visit 1, visit 2 and visit 3 are home visits and visit 4 is clinic visit. The day of recruitment will be designated as day 0; participants will then be scheduled to have a visit on day 7(V2), day 14(V3) and day 28(V4) to complete data collection.

At home visit Co investigator/ study nurse will assess demographic history, current illness, and medication history, examine symptom, check daily diary, measure body temp and body oxygen saturation, verify medication adherences and monitor adverse event/serious adverse event etc. Whole blood would be collected at V1 and V4 and sent to Central lab for cell receptor expression, function and morphology Nasal/throat swab would be collected at each visit and sent to respective laboratory for viral quantitative PCR.

If the participant discontinues treatment due to any adverse event the Investigator will arrange for follow up visit or telephonic call until AE has resolved.

However, following a confirmed COVID-19 related admission the participants would be asked to stop taking the IMP at that point.