



Clinical Trial Details (PDF Generation Date :- Fri, 27 Jan 2023 20:18:24 GMT)

CTRI Number	CTRI/2020/10/028581 [Registered on: 23/10/2020] - Trial Registered Prospectively	
Last Modified On	22/10/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Drug	
Study Design	Randomized, Parallel Group, Active Controlled Trial	
Public Title of Study	Clinical trial to study the effect of Budesonide taken through inhalation in mild COVID cases	
Scientific Title of Study	Inhalation Budesonide in the treatment of patients with mild Covid-19	
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 Tushar Patel
	Designation	Associate Professor
	Affiliation	GCS Medical College, Ahmedabad
	Address	SPARSH Chest Disease Centre, 100B Swastik Society, Opposite Samved Hospital, Navrangpura, Ahmedabad Respiratory Medicine Department, GCS Hospital, Near Chamunda Bridge, Naroda road, Ahmedabad 380025 Ahmadabad GUJARAT 380009 India
	Phone	985082672
	Fax	
	Email	drtusharpatel@yahoo.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Tushar Patel
	Designation	Associate Professor
	Affiliation	GCS Medical College, Ahmedabad
	Address	SPARSH Chest Disease Centre, 100B Swastik Society, Opposite Samved Hospital, Navrangpura, Ahmedabad Respiratory Medicine Department, GCS Hospital, Near Chamunda Bridge, Naroda road, Ahmedabad 380025 Ahmadabad GUJARAT 380009 India
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Email	drtusharpatel@yahoo.com			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Health and Family Welfare Department, Government of Gujarat			
Primary Sponsor	Primary Sponsor Details			
Name	Dr Tushar Patel			
Address	SPARSH Chest Disease Centre, 100B Swastik Society, Opposite Samved Hospital, Navrangpura, Ahmedabad			
Type of Sponsor	Other [Self]			
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 Anand Patel	GMERS Medical College and Hospital, Gotri	Old TB Hospital campus, Gotri Vadodara GUJARAT	9879771079 dranandkpatel@gmail.com
	Dr Parul Vadgama	Government Medical College and New Civil Hospital, Surat	Majura gate Surat GUJARAT	9879533318 drparulvadgama1980@gmail.com
	Dr Jigna Dave	Government Medical College and Sir Takhtasinhji General Hospital, Bhavnagar	Near ST bus stand, Jail road Bhavnagar GUJARAT	9825096289 drjignadave@yahoo.co.in
	Dr Jayeshkumar Dobariya	Synergy Superspeciality Hospital	Ayodhya Chowk, 150 Feet Ring Road Rajkot GUJARAT	9825043590 jayeshdobariya@yahoo.co.in
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	ETHICS COMMITTEE GOVERNMENT MEDICAL COLLEGE BHAVNAGAR	Approved	06/09/2020	No
	HUMAN RESEARCH ETHICS COMMITTEE, SURAT	Approved	21/10/2020	No
	INSTITUTIONAL HUMAN ETHICS COMMITTEE, VADODARA	Approved	18/08/2020	No
	SYNERGY HOSPITAL ETHICS COMMITTEE, RAJKOT	Approved	01/09/2020	No
Regulatory Clearance				



Status from DCGI	Status		Date
	Not Applicable		No Date Specified
Health Condition / Problems Studied	Health Type		Condition
	Patients		Coronavirus as the cause of diseases classified elsewhere
Intervention / Comparator Agent	Type	Name	Details
	Intervention	Budesonide, Local standard of care	Budesonide Rotacaps 200 mcg BD for 10 - 14 days depending on onset of symptoms given in addition to the local standard of care
	Comparator Agent	Local standard of care	Local standard of care for mild COVID-19 cases as provided by the centre
Inclusion Criteria	Inclusion Criteria		
	Age From	18.00 Year(s)	
	Age To	99.00 Year(s)	
	Gender	Both	
	Details	1.Patient with RT-PCR OR Rapid Antigen confirmed diagnosis of Covid-19. asymptomatic Patent with mild symptoms of less than 5 days duration. 3.Spo2>94% at room air. 4.No Radiological evidence of Pneumonia. 5 Patient aged>18years to 99Years.	
Exclusion Criteria	Exclusion Criteria		
	Details	1. Patient requiring hospitalisation. 2. Patient unable to take the drug as directed and comply with study procedure. 3.Vulnerable population(Pregnant women,Lactating women,Prisoners,Unable to consent). 4 Patients on Systemic/Inhalational Steroids.	
Method of Generating Random Sequence	Other		
Method of Concealment	Not Applicable		
Blinding/Masking	Open Label		
Primary Outcome	Outcome	Timepoints	
	Hospitalization	10 - 14 days depending on the onset of symptoms	
Secondary Outcome	Outcome	Timepoints	
	no	no	
Target Sample Size	Total Sample Size=1000		
	Sample Size from India=1000		
	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	N/A		
Date of First Enrollment (India)	23/10/2020		
Date of First Enrollment (Global)	No Date Specified		
Estimated Duration of Trial	Years=0 Months=2 Days=0		



Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	Nil
Brief Summary	<p>The randomized controlled trial aims to evaluate the effect of Inhalational Budesonide compared to standard care in mild Covid-19 illness in reducing Covid related hospital admissions. It will be undertaken at 7 different Covid treating facilities across Gujarat and enroll 1000 COVID RTPCR/ Antigen positive adult patients who are asymptomatic or having mild symptoms of less than 5 day duration, SpO₂>94% and no radiological evidence of pneumonia. 500 patients will be enrolled in intervention arm and receive self administered Budesonide rotacap 200mcg twice daily till 14 day of onset of symptoms in addition to local standard of care while other 500 in control arm will receive the regular standard of care.</p>