



Clinical Trial Details (PDF Generation Date :- Wed, 24 Feb 2021 16:21:15 GMT)

CTRI Number	CTRI/2020/07/026671 [Registered on: 18/07/2020] - Trial Registered Prospectively	
Last Modified On	18/07/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Other (Specify) [Ozone therapy]	
Study Design	Single Arm Trial	
Public Title of Study	Ozone Therapy for Covid 19 patients	
Scientific Title of Study	A pilot study for treatment of COVID-19 patients in moderate stage using intravenous administration of ozonized saline as an adjuvant treatment	
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 Alok Sharma
	Designation	Director
	Affiliation	NeuroGen Brain and Spine Institute
	Address	Chairmans room, 2nd floor, Plot 19, Sector 40, Nerul (W), Next Seawoods Grand Central Station. Off Palm Beach Road. Navi Mumbai, India. Thane MAHARASHTRA 400706. India
	Phone	9820046663
	Fax	
	Email	alok276@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Mili Arpan Shah
	Designation	President
	Affiliation	Ozone Forum of India
	Address	President of ozone forum of India, Training and education. 3rd Flr Bisleri Tower Off Western Express Highway, Andheri - Kurla Rd, Mumbai Mumbai (Suburban) MAHARASHTRA 400099 India
	Phone	9819376454
	Fax	
	Email	drmilishah@gmail.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr Jignasha Captain
	Designation	Director
	Affiliation	Ozone Forum of India
	Address	Director-Ozone Forum of India, Clinical Head, 3rd Flr Bisleri Tower Off Western Express Highway, Andheri - Kurla Rd, Mumbai Mumbai (Suburban) MAHARASHTRA 400099 India



	Phone	9967608029		
	Fax			
	Email	drjigna911@hotmail.com		
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Bisleri Charitable Trust C/o, parle bisleri pvt.Ltd western express highway, andheri (east), mumbai- 400099			
	> NeuroGen Brain and Spine Institute Plot 19, Sector 40, Nerul (W), Next Seawoods Grand Central Station. Off Palm Beach Road. Navi Mumbai- 400706. India			
Primary Sponsor	Primary Sponsor Details			
	Name	Bisleri charitable trust		
	Address	Bisleri charitable trust C/o, parle bisleri pvt.Ltd western express highway, andheri (east), mumbai- 400099		
	Type of Sponsor	Other [Charitable Trust]		
Details of Secondary Sponsor	Name	Address		
	NeuroGen Brain and Spine Institute	Plot 19, Sector 40, Nerul (W), Next Seawoods Grand Central Station. Off Palm Beach Road. Navi Mumbai- 400706. India		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr Alok Sharma	NeuroGen Brain and Spine Institute	Chairmans Room, 2nd Floor, Plot 19, Sector 40, Nerul (W), Next Seawoods Grand Central Station. Off Palm Beach Road. Navi Mumbai- 400706. India Thane MAHARASHTRA	9820046663 alok276@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Neurogen Brain and Spine Institute	Approved	15/07/2020	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	Ozone therapy	200 ml ozonized saline will be administered intravenously over 1 hour at 60 drops per minute for 8 days.	
	Comparator Agent	NA	NA	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	65.00 Year(s)		
	Gender	Both		
	Details	1. Patients confirmed to be COVID-19 positive by quantitative real		



	time polymerase chain reaction (QRT-PCR) assay 2. Patients that meet any one of the criteria of moderate stage 3. Patients who give written informed consent. 4. Age 18 – 65 years	
Exclusion Criteria	Exclusion Criteria	
Details	<ol style="list-style-type: none"> 1. Mild or severe stage 2. G6PD deficiency 3. Hyperthyroidism 4. Bleeding disorders (any coagulopathies) 5. Chronic uncontrolled illnesses such as uncontrolled diabetes, uncontrolled hypertension chronic renal failure, chronic liver disease, chronic neurodegenerative disorders, chronic heart conditions (chronic heart failure, chronic angina, previous myocardial infarction), malignancies, etc., 6. Pregnant and lactating women 7. Patients on immunosuppressant drugs 8. Patients with a history of organ transplantation 9. Patients who are participating in other clinical trials 	
Method of Generating Random Sequence	Not Applicable	
Method of Concealment	Not Applicable	
Blinding/Masking	Not Applicable	
Primary Outcome	Outcome	Timepoints
	<ol style="list-style-type: none"> a. Time to recovery on 8 point ordinal scale (Time to reach point 6-8) b. Time to Resolution of symptoms (Fever, cough, respiratory rate, shortness of breath) c. PAO₂/FiO₂ d. Chest X-ray – Day 1, 7 & 14 e. Inflammatory Biomarkers: C- reactive Protein, IL-6, Ferritin, LDH, D-Dimer e. Percentage of patients declining to serious stage at the end of 14 days f. Percentage of patients improving to mild stage at the end of 14 days 	Day 1 Day 3 Day 6 Day 10 Day 14
Secondary Outcome	Outcome	Timepoints
	<ol style="list-style-type: none"> a. Oxygen saturation index: SPO₂ / FiO₂ b. Total blood count: WBC, Hemoglobin, RBC c. Liver Function Test: SGOT, SGPT, Total and Direct Bilirubin d. Renal Function Test: BUN Creatinine e. Serum electrolytes f. Cardiac Function: Troponin and ECG g. Percentage Mortality h. Cumulative incidence of serious adverse events i. Duration of hospitalization j. Duration of new oxygen use k. SOFA score 	Day 1 Day 3 Day 6 Day 10 Day 14
Target Sample Size	Total Sample Size=10 Sample Size from India=10 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)	27/07/2020	



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>India has 13,295 active COVID-19 cases with death toll reaching 519 as of 19th April 2020. There is an urgent need to explore novel options of treatment for COVID-19. Despite standard treatment, 20% of patient's progress to moderate stage out of which 5% deteriorate to severe stage and the mortality rate is 3%. Ozone therapy, an integral part of Naturopathic medicine extensively been used for treating chronic diseases since many years. COVID-19 exhibits multimodal pathology by inducing a 'cytokine storm' primed to exacerbate the inflammatory response, depleted oxygenation and viral infection leading to pneumonia, edema, respiratory failure and eventually, death. Ozone therapy has been shown to mitigate inflammatory cytokine storms in a variety of disorders, including respiratory disorders. It has potent antiviral, anti-inflammatory and immunomodulatory effects. Recent reports from Balearic Islands reveals that no new cases of COVID-19 following the administration of ozone therapy by a clinic in Spain. Several clinical trials are under way for testing the safety and efficacy of ozone therapy against COVID-19, with no reports of adverse events so far. The present study is proposed to evaluate the utility of ozone therapy as an adjuvant along with standard care in control of disease progression in patients COVID-19.</p>