Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 09:32:25 GMT)

CTRI Number	CTRI/2020/06/026256 [Registered on: 30/06/2020] - **Trial Registered Prospectively**
Last Modified On	30/06/2020
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Case Control Study
Study Design	Other
Public Title of Study	Resveratrol and copper for the treatment of COVID-19 pnuemonia.
Scientific Title of Study	Routine use of over-the-counter Nutraceuticals, Resveretrol-Copper with standard treatment in Hospitalized Patients With Pneumonia/ Acute Respiratory Distress Syndrome Due To SARS-CoV-2 (Covid-19)- Retrospective Analysis

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	Rosemarie Desouza
Designation	Professor
Affiliation	T.N.M.C and B.Y.L.Nair Hospital
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Details Contact Person (Scientific Query)

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Email	drrosemariedesouza@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Nil

Primary Sponsor

Primary Sponsor Details	
Name	TopiwalaNational Medical College and BYL Nair charitable Hospital
Address	Dr Anandrao Nair Marg, Mumbai Central, Mumbai, Maharashtra 400008
Type of Sponsor	Government medical college

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
Rosemarie Desouza	T.N.M.C and B.Y.L.Nair Hospital	First Floor, Department of Medicine, Dr.A.L.Nair Road, Mumbai-400008 Mumbai MAHARASHTRA	9820056230 drrosemariedesouza@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Topiwala National College and B.Y.L. Nair CH. Hospital	Approved	23/06/2020	Yes

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

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	Male and non-pregnant female patients 1.Have positive reverse-transcriptase–polymerase polymerase chain-reaction (RT-PCR) in a diagnostic specimen 2.Have pneumonia confirmed by chest imaging 3.oxygen saturation (Sao2) of 94% or less while they were breathing ambient air 4.have either normal levels of haematological, liver and renal functions, and electrolytes OR no worse than Grade 3 (CTCAE Version 5.0) abnormalities in any of these parameters

Exclusion Criteria

Exclusion Criteria	
Details	Asymptomatic or only mildly symptomatic

Method of Generating Random Sequence	Not Applicable
Method of	Not Applicable

Concealment	
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
To retrospectively access the clinical outcomes in the patients receiving R-Cu along with standard treatment versus those who received standard treatment.	10 Days

Secondary Outcome

Outcome	Timepoints
NIL	NIL

Target Sample Size	**Total Sample Size=**230 **Sample Size from India=**230 **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)	10/07/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**1 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL

Brief Summary

The COVID-19 pandemic has taken centre stage in the global search for drugs and vaccines for its prevention or cure. The purpose of this study is to access the clinical outcomes in patients receiving over-the-counter nutraceuticals - Resveratrol and Copper (R-Cu) for the treatment of severe COVID-19 infection. Resveratrol is a well-researched anti-oxidant plant polyphenol. A research group at Tata Memorial Centre, Mumbai, has shown that the combination of Resveratrol and Copper may be effective in the treatment of severe sepsis and Acute Respiratory Distress Syndrome (ARDS). Since sepsis and ARDS are the end stage complication of COVID-19 leading to death, it was hypothesised that R-Cu could be effective in preventing death due to severe COVID-19 infection. A total of 30 SARS-CoV-2 (COVID-19) hospitalized patients with pneumonia / ARDS were administered R-Cu in addition to standard care during the period 23-04-2020 to 30-05-2020 at Topiwala National Medical College and B.Y.L

Nair Hospital, Mumbai. Both nutraceuticals were used at doses several fold less than their daily permissible limit, obviating any safety concerns related to their use. A retrospective, case-control study is being planned to compare the outcomes of these 30 patients against 200 matched controls who did not receive R-Cu. By doing this study, we will be able to demonstrate the utility of R-Cu in patients with pneumonia / ARDS due to COVID-19 in addition to generating hypothesis for a future randomized controlled trial of this intervention in severe COVID-19 infection.