Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 10:59:44 GMT)

CTRI Number	CTRI/2020/07/026515 [Registered on: 13/07/2020] - **Trial Registered Prospectively**
Last Modified On	13/07/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Multiple Arm Trial
Public Title of Study	Randomized Controlled Trial Of Resveretrol-Copper Or Sodium-Copper-Chlorophyllin Vs Standard Treatment In Mild Covid-19 infection with Cancer Patients.
Scientific Title of Study	A Phase-III, Open Label, Randomized Controlled Trial of Resveretrol-Copper Plus Standard Treatment Or Sodium-Copper-Chlorophyllin Plus Standard Treatment Versus Standard Treatment in Cancer patients with SARS-CoV-2 Infection who are Asymptomatic Or Mildly Symptomatic for 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	Pankaj Chaturvedi
Designation	Professor
Affiliation	Tata Memorial Hospital,Mumbai
Address	Thirteenth floor, Department of Head and Neck Surgery, Tata Memorial Hospital, Dr Ernest Borges Rd, Parel East, Parel, Mumbai, Maharashtra Mumbai MAHARASHTRA 400012 India
Phone	9869486912
Fax	
Email	chaturvedi.pankaj@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	VIKRAM GOTA
Designation	Scientific Officer F
Affiliation	ACTREC, Tata Memorial Centre
Address	Room No. 102,Khanolkar Shodhika,ACTREC-TMC,Sector No.22,Kharghar,Navi Mumbai Raigarh MAHARASHTRA 410210 India
Phone	7715019117
Fax	
Email	vikramgota@gmail.com

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Address	Room No. 102,Khanolkar Shodhika,ACTREC-TMC,Sector No.22,Kharghar,Navi Mumbai Raigarh MAHARASHTRA

	410210 India
Phone	7715019117
Fax	
Email	vikramgota@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> NIL

Primary Sponsor

Primary Sponsor Details	
Name	Tata Memorial Centre
Address	Dr Ernest Borges Rd, Parel East, Mumbai, Maharashtra 400012
Type of Sponsor	Research institution and hospital

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
Pankaj Chaturvedi	Tata Memorial Hospital	Thirteenth Floor, Department of Head and Neck Surgery, Tata Memorial Hospital, Dr Ernest Borges Rd, Parel East, Parel, Mumbai, Maharashtra 400012 Mumbai Mumbai MAHARASHTRA	9869486912 chaturvedi.pankaj@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Tata Memorial Centre Institutional ethics committee II	Approved	30/06/2020	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	Resveratrol-Copper tablets	Patients will receive Resveratrol-Copper tablets (1 tablet 4 times per day) from the date of randomization to the day of discharge or death, whichever is earlier. Patients in this arm can also receive all standard treatment that the treating team considers appropriate including any other antibiotic, antibacterial, antiviral or antimicrobial drugs.
Intervention	Chlorophyllin tablets	Patients will receive oral Chlorophyllin tablets daily under

		fasting conditions at a dose of 750 mg OD from the date of randomization to the day of discharge or death, whichever is earlier. Patients in this arm can also receive all standard treatment that the treating team considers appropriate including any other antibiotic, antibacterial, antiviral or antimicrobial drugs.
Comparator Agent	Standard treatment	Patients in this arm can receive all standard treatment that the treating team considers appropriate including any other antibiotic, antibacterial, antiviral or antimicrobial drugs.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1.Male and non-pregnant female cancer patients 18 years of age or older. 2. Positive reverse-transcriptase–polymerase polymerase chain-reaction (RT-PCR) in a diagnostic specimen 3. Either asymptomatic or have only mild symptoms ((cough and/or fever and/or sore throat and/or other upper respiratory symptoms) at the time of study inclusion 4.Oxygen saturation of >94% while breathing ambient air, if this is measured 5.Either normal levels of haematological, liver and renal functions, and electrolytes OR no worse than Grade 1 (CTCAE Version 5.0) abnormalities in any of these parameters. 6. Patients with high blood sugar or glycosylated haemoglobin, of any degree will be eligible 7. Arterial blood gas, if done, should have normal values of pH, PO2, PCO2 and bicarbonate level.

Exclusion Criteria

Exclusion Criteria	
Details	1.Cancer diagnosis not proven 2. Have pneumonia confirmed by chest imaging, 3. Have oxygen saturation (Sao2) of 94% or less while they were breathing ambient air 4.Have any Grade 2 or worse laboratory abnormality, including haematological, renal, liver, electrolyes.

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

Primary Outcome

Outcome	Timepoints
the proportion of patients who suffer clinical deterioration OR viral persistence at Day 10 from the date of randomization (excluding the date of randomization).	10 Days

Secondary Outcome

Outcome	Timepoints
1.All-cause mortality at 28 days after randomization (28-day mortality)	1.Day 28 2.Day 28

	2.Overall Survival times in days (with any-cause death constituting an event) 3.The proportion of patients with virological positivity. 4. Translational, including biomarker-related, research in banked bio-specimens. | 3.Day 10 4.Day 0,5,10,Discharge
Target Sample Size	**Total Sample Size=**300 **Sample Size from India=**300 **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)	22/07/2020
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	NIL
Brief Summary	At present, there are no specific antiviral drugs or vaccine against COVID-19 disease for potential therapy on humans. It will be worthwhile testing SARS-CoV-2 positive patients with cancer with new molecules i.e. resveretrol-copper and sodium-copper-chlorophyllin which may provide a solution to treat the pathology of COVID-19 with its possible mechanism of action. Research has shown that cfCh released from dying host cells following microbial infection leads to bystander host cell apoptosis and inflammation which is perpetuated in a vicious cycle. It can be broken by administration of R-Cu, which inactivates cfCh released from dying cells leading to amelioration of sepsis which is the end stage of COVID-19 as well as it degrades the SARS-CoV2 RNA through which it may show amelioration in viral load and clinical symptoms which may likely to show improvement in clinical condition. The objectives of this study are to assess whether resveretrol-copper and/or sodium-copper-chlorophyllin will reduce the virological load and reduce 28-day mortality in asymptomatic or mildly symptomatic COVID-19 cancer patients. This study will be carried out in 300 SARS-CoV positive cancer patients randomly assigned in 1:1:1 ratio to resveratrol-copper + standard treatment (Arm 1), sodium copper chlorophyllin + standard treatment (Arm 2) or standard treatment alone (Arm 3). The proportion of ‘Failures’ (persistence of viral load at day 10 or clinical deterioration on or before day 10) will be compared between Arm 1 and Arm 3 & between Arm 2 and Arm 3, using chi-square test and the odds ratio for ‘Failure’ will be computed in the 2 comparisons, with their respective 95% CI. The proportion of deaths (28 days mortality) will be compared between Arm 1 and Arm 2 & between Arm 2 and Arm 3, by chi-square tests and odds ratio for deaths (with their 95% CI) calculated for the 2 comparisons.