Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 11:31:33 GMT)

CTRI Number	CTRI/2020/06/026194 [Registered on: 28/06/2020] - **Trial Registered Prospectively**
Last Modified On	08/02/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Preventive
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Using N-acetylcysteine as therapeutic drug for COVID-19 patients.
Scientific Title of Study	A randomized, double blind, placebo controlled, comparative study to investigate the efficacy of N-acetylcysteine in COVID-19 patients with standard therapy.

Secondary IDs if Any

Secondary ID	Identifier
NCT04374461	ClinicalTrials.gov

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

Details of Principal Investigator	
Name	Neha Jaiswal
Designation	principal Investigator
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> 4. Index Medical College Hospital & Research Centre, Index City,Gram Morodhat Nh-59 A, Nemawar Road Near Khudel Indore,MP

Primary Sponsor

Primary Sponsor Details	
Name	Index Medical College and research centre Indore
Address	Index Medical College and research centre, Indore
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
Dr Neha Jaiswal	NAME OF SITE: Index Medical College Hospital & Research Centre	SITE ADDRESS: The proposed study will be conducted in corona isolation wards of Index hospital Indore. The hospital is designated as 'Red Zone' hospital for treatment of corona patients. Indore MADHYA PRADESH	8949988510 jaisneha411@gmil.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
IEC, Index medical college Indore	Approved	18/06/2020	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
Intervention	N-acetylcysteine	N-acetyl cysteine (NAC)oral administration in dose of 600 mg daily twice a day for 10 days.
Comparator Agent	glucose capsule	similar capsule containing glucose 600 mg will be given oral daily twice a day for 10 days.

Inclusion Criteria

Inclusion Criteria	
Age From	10.00 Year(s)
Age To	55.00 Year(s)
Gender	Both
Details	patients of both genders who aged between 10 years to 55 years

	with confirmation of COVID-19 infection through RT-PCR test. Mild to moderate severity of disease who are willing to participate in study by giving written informed consent.

Exclusion Criteria

Exclusion Criteria	
Details	seriously ill patients requiring ventilators support. Children below 10 years, adults > 55 years of age.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	On-site computer system
Blinding/Masking	Double Blind Double Dummy

Primary Outcome

Outcome	Timepoints
1. Effect of NAC in the study group on alleviating patient's signs and Symptoms of COVID-19 in forms of severity and duration. 2. Rate of cure from the disease as measured by negative results of RT-PCR test on nasopharyngeal swabs	5-7days from start of dose administration

Secondary Outcome

Outcome	Timepoints
1. Incidence of the adverse effects in both the group. 2. Association of age and gender with the clinical outcome in COVID-19 patients. 3. Progression of the patient towards severity of disease.	1-10 days from start of dose administration

Target Sample Size	**Total Sample Size=**200 **Sample Size from India=**200 **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)	30/06/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Other (Terminated)
Recruitment Status of Trial (India)	Other (Terminated)
Publication Details	

Brief Summary

COVID-19 is a universal emergency, and is characterized by high morbidity and mortality. In this project we aim to examine the effect of N-acetycysteine on alleviating signs and symptoms of SARS CoV-2 infection. This study will be a randomized, double blind placebo-controlled clinical trial conducted in the corona isolation wards of Index hospital Indore which is already designated as 'Red Zone' hospital for treatment of the COVID patients.

Subjects:

100 patients will be selected from the admitted patients undergoing COVID-19 treatment in corona ward after signing the informed consent. Stratified patients will be randomly assigned in either NAC group (n=50) or control group (placebo) (n=50). The NAC group will receive N-acetyl cysteine along with the conventional treatment for SARS CoV-2 infection whereas placebo group will be given sugar coated tablets added up with regular conventional treatment.

The symptomatic treatment containing of an expectorant, and will be given to both the groups as and when required. Diary record of all the medications given will be maintained. Patients in the NAC group will receive 600mg/day oral NAC doses for 10 days. Patients will be monitored for the incidence of NAC related side effects and drug interaction. Increase and decrease of NAC doses will be done during the pilot experiment. RT PCR of nasopharyngeal swabs will be performed. Data will be recorded and analyzed for primary and secondary outcomes and interpretations will be made in concern with effectiveness of NAC in COVID treatment.