Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy of N-Acetylcysteine in severe COVID-19 patients: a randomized controlled phase III clinical trial

Protocol summary

Study aim
This study aims to investigate the effect of N-Acetylcysteine on the recovery process of severe COVID-19 patients.

Design
Concealed, randomized, single blinded, phase 3 controlled clinical trial with two arm parallel group design of 40 patients, using the placebo in the control group.

Settings and conduct
This study will be performed in Shahid Mohammadi Hospital in Bandar Abbas city. Patients enter the study after obtaining written consent. Patients are randomly assigned to one of the intervention or control groups with the placebo. Also, patients will not know which group they belong to. (single blinded)

Participants/Inclusion and exclusion criteria
All COVID-19 patients admitted to the intensive care unit of Shahid Mohammadi Hospital in Bandar Abbas, whose PCR test results are positive for SARS-Cov-2 and signs the written consent of the study will be included in the study. Patients will be excluded from the study if they have a history of hypersensitivity to N-Acetylcysteine, pregnancy, or refuse to participate in the study.

Intervention groups
Patients are divided into two groups. In group A, the standard treatment for COVID-19 patients with N-Acetylcysteine is prescribed. In group B, patients receive standard COVID-19 treatment with the placebo.

Main outcome variables
Patient's clinical symptoms and laboratory examinations.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200509047364N3**
Registration date: **2021-02-20, 1399/12/02**
Registration timing: **prospective**
Last update: **2021-02-20, 1399/12/02**
Update count: **0**

Registration date
2021-02-20, 1399/12/02

Registrant information

Name
Dariush Hooshyar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-02, 1399/12/12

Expected recruitment end date
2021-04-01, 1400/01/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of N-Acetylcysteine in severe COVID-19 patients: a randomized controlled phase III clinical trial

Public title
The effect of N-Acetylcysteine on COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All COVID-19 patients whose disease has been confirmed by the PCR test for SARS-Cov-2. Having one of the criteria for severe COVID-19 disease includes tachypnea (respiration rate> 30 per minute), hypoxemia (O2 ≤ saturation, arterial oxygen partial pressure ratio <300), pulmonary infiltration (> 50% of lung area during 24 48 h), LDH> 245 U / l, Progressive lymphopenia. Hospitalized in the intensive care unit. Signing the written consent of the study participant.

Exclusion criteria:

Known allergy or hypersensitivity to N-Acetylcysteine. Pregnancy The participant refused to participate in the continuation of the study.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Before assigning groups to individuals eligible to participate in the study, informed consent is completed for grouping individuals. the person who has no role in admitting patients and assigning patients to random codes preparing random sequences using online tools (https://www.sealedenvelope.com/) and by permuted block randomization method. Individualized random allocation is done in blocks with sizes 2 and 4, and without stratification. eligibility criteria are monitored by the person responsible for admitting patients. Codes in a random sequence are assigned to patients by the treatment team without knowing that each code is in the intervention or placebo group. Patient codes are then matched to randomly generated sequence information for interventions. (randomization concealment is done by the treatment team without informing the person responsible for admitting patients and the person who prepared the random sequence.)

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, all participants are aware of participating in this study and enter the study with their consent. All participants are unaware of which group of this study they are in and after grouping patients in the groups, Patients receive N-Acetylcysteine in the treatment group and receive a placebo in the control group. The lead researcher, health care personnel, data collection officials, and those who evaluate the outcome are aware of the grouping of patients. Those who prepare the draft of the article are unaware of the groupings if they do not cooperate in the above cases.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Deputy of Research and Technology, Hormozgan University of Medical Sciences, Shahid Chamran Boulevard, Bandar Abbas, Hormozgan, Iran

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Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2021-02-14, 1399/11/26

Ethics committee reference number

IR.HUMS.REC.1399.539

Health conditions studied

1

Description of health condition studied

Laboratory confirmed COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Patient's clinical condition

Timepoint

At the time of admission to the hospital (Before starting the intervention) and on the 14th day of hospitalization or the day of discharge

Method of measurement

Clinical examinations

2

Description

Length of Intensive Care Unit admission

Timepoint

At the time of admission to the hospital (Before starting the intervention) and on the 14th day of hospitalization

or the day of discharge

Method of measurement

Record patient information

Secondary outcomes

1

Description

Respiratory rate

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pulse oximeter

2

Description

Oxygen saturation state

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pulse oximeter

3

Description

Lung infiltration status

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Chest X-ray

4

Description

Lactate Dehydrogenase(LDH) level's

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pathobiology laboratory

5

Description

C-reactive protein(CRP) level's

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pathobiology laboratory

6

Description

Lymphocyte count

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pathobiology laboratory

7

Description

Platelet count

Timepoint

At the beginning of the study (before the intervention) and day 14 after the intervention or the day of patient's discharge.

Method of measurement

Pathobiology laboratory

Intervention groups

1

Description

Intervention group: Group A receives standard drug therapy based on the treatment protocols of the National Committee COVID-19 and N-Acetylcysteine (Exi-Nac 2g/10ml AMP (EXIR pharmaceutical company)) at a dose of 300 mg/kg equivalent to 20 g as a slow single intravenous injection on the first day of hospitalization. Vital signs of patients are also checked at regular intervals and frequently. Standard pharmacotherapy according to the treatment protocols of the National Committee of COVID-19 includes Hydroxychloroquine / Chloroquine Phosphate: Hydroxychloroquine sulfate tablets 200 mg or chloroquine phosphate tablets 250 mg (equivalent to 150 mg base dose) 2 tablets every 12 hours on the first day and then one tablet every 12 hours for at least 7 days and up to 14 days. One of the following medications at the discretion and diagnosis of the treating physician: kaletra tablets (Lopinavir / Ritonavir) 50/200 mg every 12 hours 2 pieces after meals for at least 7 days and a maximum of 14 days. Tablets (Atazanavir / Ritonavir) 300/100 One tablet daily with food or Atazanavir 400 mg daily for at least 7 days and up to 14 days.

Category

Treatment - Drugs

2

Description

Control group: Group B receives standard drug therapy based on the treatment protocols of the National COVID-19 Committee and placebo as a slow single intravenous injection on the first day of hospitalization. Standard pharmacotherapy according to the treatment protocols of the National Committee of COVID-19 includes Hydroxychloroquine / Chloroquine Phosphate: Hydroxychloroquine sulfate tablets 200 mg or

chloroquine phosphate tablets 250 mg (equivalent to 150 mg base dose) 2 tablets every 12 hours on the first day and then one tablet every 12 hours for at least 7 days and up to 14 days. One of the following medications at the discretion and diagnosis of the treating physician: kaletra tablets (Lopinavir / Ritonavir) 50/200 mg every 12 hours 2 pieces after meals for at least 7 days and a maximum of 14 days. Tablets (Atazanavir / Ritonavir) 300/100 One tablet daily with food or Atazanavir 400 mg daily for at least 7 days and up to 14 days.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mohammadi Hospital

Full name of responsible person
Dr. Arash Rahimi

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Boulevard of the Islamic Republic of Iran, Bandar Abbas

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bandare-abbas University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Dariush Hooshyar

Position
Student of Medicine

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Assistant Professor

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Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available