

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the efficacy of inhaled heparin/N-acetylcysteine, N-acetylcystein alone, and placebo for the treatment of COVID-19 patients admitted to the hospital

Protocol summary

Study aim

Comparison of the efficacy of inhaled heparin/N-acetylcysteine, N-acetylcystein alone, and placebo for the treatment of COVID-19 patients

Design

Three-arm double-blind phase-III randomized controlled trial with parallel groups with allocation concealment on 75 patients, using sealed envelopes for randomization

Settings and conduct

Patients with confirmed COVID-19 based on the PCR test admitted to the ICU of Payambar Azam Hospital, Bandar Abbas, Iran from March 11 to April 4, 2022 will be included according to the inclusion and exclusion criteria. This study is a double-blind randomized controlled trial so that neither the patients nor the investigator will be aware of the groupings. Patients will be randomly allocated to 3 groups (n=25) using sealed envelopes: The first group will receive the protocol treatments and 2 ml heparin from a 5000 IU vial (DarouPakhsh Co., Iran) plus 3 ml of NAC 20% (DarouPakhsh Co., Iran) amounting to an overall 5-ml nebulizer solution. The second group will receive 3 ml of NAC 20% plus 2 ml of distilled water and the third group 5 ml of distilled water. All groups will receive these treatments every 4 hours every day for 7 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of COVID-19 based on the results of the PCR test Admission to the intensive care unit Exclusion criteria: Hypersensitivity to heparin and N-acetyl cysteine Coagulopathies

Intervention groups

The first group, the protocol treatments plus 2 ml heparin from a 5000 IU vial plus 3 ml of NAC 20% amounting to an overall 5-ml nebulized solution every 4 hours every day for 7 days The second group, the protocol treatments plus 3 ml of NAC 20% plus 2 ml of distilled water every 4 hours every day for 7 days The

third group, the protocol treatments plus 5 ml of distilled water every 4 hours every day for 7 days.

Main outcome variables

Duration of ICU stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201210049672N1**

Registration date: **2022-03-17, 1400/12/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-17, 1400/12/26**

Update count: **0**

Registration date

2022-03-17, 1400/12/26

Registrant information

Name

Bibimona Razavi

Name of organization / entity

Hormozgan University of Medical Sciences, Faculty of Medicine

Country

Iran (Islamic Republic of)

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+98 76 3371 0370

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bibimonarazavi.hums@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-11, 1400/12/20

Expected recruitment end date

2022-04-04, 1401/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of inhaled heparin/N-acetylcysteine, N-acetylcystein alone, and placebo for the treatment of COVID-19 patients admitted to the hospital

Public title
Comparison of inhaled heparin/N-acetylcysteine, N-acetylcystein alone, and placebo for the treatment of COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Definitive COVID-19 diagnosis based on PCR results
Admission to the intensive care unit
Exclusion criteria:
Hypersensitivity to heparin and N-acetyl cysteine
Coagulopathies

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: 25

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with individuals as units of randomization along with allocation concealment: 75 unclear envelopes and 75 cards with the names of the groups (A, B, C) will be prepared (25 cards for each group). The cards will be put into the envelopes and the envelopes will be sealed and provided to the investigator. Upon entrance of each patient to the study, the envelopes will be shuffled and one will randomly be selected. The patient will be allocated to group A, B, or C based on the card inside the selected envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
A total of 5-ml vials will be prepared by an individual not involved in the study. Each 25 vials will be prepared based on the instructions for any of the three study groups. Then, a label indicating A, B, or C will be

attached to each vial. The vials will be kept in an appropriated place and the investigator, the participants, the nurses responsible for drug administration, and all other individuals involved in the study will be unaware of the content of vials.

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
Imam Hossein Blvd., across from Kargaran Sports Complex, Faculty of Medicine
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2021-04-19, 1400/01/30
Ethics committee reference number
IR.HUMS.REC.1400.022

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
B34.2
ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Intensive care unit length of stay
Timepoint
At the end of the study
Method of measurement
Checklist

Secondary outcomes

1

Description

Tracheal intubation requirement

Timepoint

Any time during the study

Method of measurement

Checklist

2

Description

Mechanical ventilation requirement

Timepoint

Any time during the study

Method of measurement

Checklist

3

Description

Death

Timepoint

Any time during the study

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group: Protocol treatments + 2 ml heparin from the 5000 IU vial and 3 ml N-acetyl cysteine 20% amounting to a total of nebulized 5 ml solution, every 4 hours, daily for 7 days

Category

Treatment - Drugs

2

Description

Intervention group: Protocol treatments + 3 ml N-acetyl cysteine 20% and 2 ml distilled water amounting to a total of nebulized 5 ml solution, every 4 hours, daily for 7 days

Category

Treatment - Drugs

3

Description

Control group: Protocol treatments + nebulized 5 ml distilled water , every 4 hours, daily for 7 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Payambar Azam Educational and Medical Complex

Full name of responsible person

Bibimona Razavi

Street address

Jomhuri Eslami Blvd., Payambar Azam Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research Hormozgan University of Medical Sciences

Full name of responsible person

Teamur Aghamolaei

Street address

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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

Vice-Chancellery for Research Hormozgan 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

Bibimona Razavi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available