Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the efficacy of inhaled heparin/N-acetylcysteine, N-acetylcystein alone, and placepo 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 placepo 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
Incision 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
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Iran (Islamic Republic of)
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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 placepo for the treatment of COVID-19 patients admitted to the hospital

Public title

Comparison of inhaled heparin/N-acetylcysteine, N-acetylcystein alone, and placepo 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
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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
Imam Hossein Blvd., across from Kargaran Sports Complex
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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
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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