Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluating the effect of intravenous N-acetyl cysteine versus placebo in the treatment of patients with mild and moderate acute respiratory distress syndrome caused by COVID-19: A double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of intravenous N-acetyl cysteine versus placebo in the treatment of patients with mild and moderate acute respiratory distress syndrome caused by COVID-19

Design

This is a double-blind randomized clinical trial, phase II, in which 92 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with mild and moderate acute respiratory distress syndrome caused by COVID-19 referring to the Besat Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 70 years, Being hospitalized in the intensive care unit in less than the past 48 hours, Mild to moderate acute respiratory distress syndrome due to COVID-19, Bilateral pulmonary infiltration in chest X-ray or CT-scan, Respiratory distress with more than 24 breathe per minute Exclusion criteria: Pregnancy or breastfeeding, Cardiopulmonary edema, Severe acute respiratory distress syndrome, Using antioxidant drugs, Chronic liver or renal disease, Contraindication of N-acetyl cysteine

Intervention groups

Intervention group: Routine care plus intravenous infusion of N-acetyl cysteine 40 mg/kg/day diluted in 100 ml dextrose 5% for 3 days Control group: Routine care plus intravenous infusion of 100 ml dextrose 5% daily for 3 days

Main outcome variables

Primary outcome: Need for mechanical ventilation, the patient's clinical status, the mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N355**
Registration date: **2020-05-18, 1399/02/29**
Registration timing: **prospective**

Last update: **2020-05-18, 1399/02/29**
Update count: **0**

Registration date

2020-05-18, 1399/02/29

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-04, 1399/03/15

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of intravenous N-acetyl cysteine versus placebo in the treatment of patients with mild and moderate acute respiratory distress syndrome caused by COVID-19: A double-blind randomized clinical trial

Public title

Evaluating the effect of intravenous N-acetyl cysteine versus placebo in the treatment of patients with mild and moderate acute respiratory distress syndrome caused by COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 70 years, Being hospitalized in intensive care unit in less than past 48 hours, Mild to moderate acute respiratory distress syndrome due to COVID-19, Bilateral pulmonary infiltration in chest X-ray or CT-scan, Respiratory distress with more than 24 breathe per minute

Exclusion criteria:

Pregnancy or breastfeeding, Cardiopulmonary edema, Severe acute respiratory distress syndrome, Using antioxidant drugs, Chronic liver or renal disease, Contraindication of N-acetyl cysteine

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.UMSHA.REC.1399.153

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Need to mechanical ventilation

Timepoint

Within 28 days after the intervention

Method of measurement

By physical examination

2

Description
The patient's clinical status
Timepoint
Within 28 days after the intervention
Method of measurement
Based on the World Health Organization's 7-score system

3

Description
Mortality rate
Timepoint
Within 28 days after the intervention
Method of measurement
Based on medical document

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine care plus intravenous infusion of N-acetyl cysteine 40 mg/kg/day diluted in 100 ml dextrose 5% for 3 days
Category
Treatment - Drugs

2

Description
Control group: Routine care plus intravenous infusion of 100 ml dextrose 5% daily for 3 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital in Hamadan city
Full name of responsible person
Dr Abbas Taher
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Dr Abbas Taher
Position
Anesthesiologist
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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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