

# 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)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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**

Besat Hospital, Shahed Square

##### **City**

Hamadan

##### **Province**

Hamadan

##### **Postal code**

6517838695

##### **Phone**

+98 81 3364 0030

##### **Email**

t\_anesthesia@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Hamedan University of Medical Sciences

##### **Full name of responsible person**

Dr. Saeid Bashirian

##### **Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### **City**

Hamadan

##### **Province**

Hamadan

##### **Postal code**

6517838695

##### **Phone**

+98 81 3838 0717

##### **Email**

info.research@umsha.ac.ir

#### **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**

Anesthesiology

##### **Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

##### **City**

Hamadan

##### **Province**

Hamadan

##### **Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

t\_anesthesia@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Mehrpooya

**Position**

Clinical Pharmacologist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

m\_mehrpooya2003@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**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