

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Investigation of the effect of NAC on the treatment of acute respiratory distress syndrome in patients undergoing mechanical ventilation in the intensive care unit

Protocol summary

Study aim

Evaluate efficacy of f NAC on the treatment of acute respiratory distress syndrome in patients undergoing mechanical ventilation

Design

Randomized clinical trial including control with a parallel group designed of 60 patients, two phase

Settings and conduct

60 Patients were randomly divided into two equal groups: the NAC group, which received routine medical care as well as 150 mg/kg day one and therapy will be continuous as 50 mg/kg between 2-4 days. The control group will receive routine medical care. Follow-up: The following intraoperative clinical variables were recorded: The primary objective and endpoint is to assess the effect of iloprost on the improvement of oxygenation (PaO₂/FiO₂ ratio) in patients with ARDS. -PEEP ratio for more effective mechanical ventilation -APACHE II score -ICU length of stay -Duration of mechanical ventilation support - mortality rate and -FRC the parameter will be recorded within 4 days. Place of Study: Imam Khomeini Hospital; Ahvaz; Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mechanical ventilation more than 48 hours PaO₂/FiO₂ ratio $\geq$ 200 mmHg PEEP $\geq$ 10 cm H₂O Bilateral Pulmonary infiltrates on the chest x ray
Exclusion criteria: patients who not signed an informed consent form patients with cardiac and pulmonary disease pulmonary hypertension Viral and bacterial diseases including acquired immunodeficiency syndrome (AIDS), hepatitis, pulmonary tuberculosis History of chemotherapy The use of immunosuppressive drugs within the last three months History of organ transplantation within the last two years Proven brain death Sensitivity to NAC

Intervention groups

the NAC group, which received routine medical care as

well as 150 mg/kg day one through the intravenous injection and therapy will be continuous as 50 mg/kg between 2-4 days.

Main outcome variables

balance of FiO₂/ PAO₂ as well as PEEP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200425047201N1**

Registration date: **2020-05-06, 1399/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-08, 1400/03/18**

Update count: **2**

Registration date

2020-05-06, 1399/02/17

Registrant information

Name

Mojtaba Ghorbi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3235 0348

Email address

ghorbi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2020-05-30, 1399/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of NAC on the treatment of acute respiratory distress syndrome in patients undergoing mechanical ventilation in the intensive care unit

Public title

Investigation of the effect of NAC on the treatment of acute respiratory distress syndrome in patients undergoing mechanical ventilation in the intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Mechanical ventilation more than 48 hours
PaO₂/FiO₂ ratio $\geq$ 200 mmHg PEEP $\geq$ 10 cm H₂O Bilateral pulmonary infiltrates on the chest x ray

Exclusion criteria:

Patients who signed an informed consent form Patients with cardiac and pulmonary disease Pulmonary hypertension Viral and bacterial diseases including acquired immunodeficiency syndrome (AIDS), hepatitis, pulmonary tuberculosis History of chemotherapy The use of immunosuppressive drugs within the last three months Sensitivity to NAC History of transplantation within the last two years

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Care provider
- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be done by simple random method, after identifying eligible patients, they will be randomly assigned a three-digit proprietary code. The last digit on the right determines the patient group. If the figure is 0,1,2,3,4 it will be placed in the intervention group (NAC) and if the figure is 5,6,7,8,9 it will be placed in the control group

Blinding (investigator's opinion)

Double blinded

Blinding description

Person in charge of care and the data analyzer are not aware of the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethic Committee of Joundishapour University of Medical Sciences

Street address

School of Medicine, Ahvaz Jundishapur University of Medical Sciences, Golestan Ave, Ahvaz, Khuzestan, Iran

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2019-08-16, 1398/05/25

Ethics committee reference number

IR.AJUMS.REC.1398.389

Health conditions studied**1****Description of health condition studied**

Acute respiratory distress syndrome (ARDS)

ICD-10 code

J80

ICD-10 code description

Acute respiratory distress syndrome

Primary outcomes**1****Description**

Percent of respiratory index in questioner no 1

Timepoint

The NAC group, which received routine medical care as well as 150 mg/kg day one through the intravenous injection and therapy will continue as 50 mg/kg between 2-4 days.

Method of measurement

Mechanical ventilator apparatus

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the NAC group, which received routine medical care as well as 150 mg/kg day one through the intravenous injection and therapy will contentious as 50 mg/kg between 2-4 day.

Category

Other

2

Description

Control group: Receive routine medical care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khumaini Hospital, Ahvaz

Full name of responsible person

Mojtaba Ghorbi- Mahbubeh Rashidi

Street address

Imam Khomeini University Hospital, Azdehgan Ave,
Ahvaz, Khuzestan, Iran

City

Ahvaz

Province

Khuzestan

Postal code

6193673111

Phone

+98 61 3222 2922

Email

Imamhospital@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mahboobeh Rashidi

Street address

School of Medicine, Ahvaz Jundishapur University of
Medical Sciences, Golestan Ave, Ahvaz, Khuzestan,
Iran

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8571

Email

rashidi-m@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mojtaba Ghorbi

Position

Medical Student of Anesthesiology and pain

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

School of Medicine, Ahvaz Jundishapur University of
Medical Sciences, Golestan Ave, Ahvaz, Khuzestan,
Iran

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 41 3235 0348

Email

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Person responsible for scientific inquiries

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Article

When the data will become available and for how long

2021

To whom data/document is available

Researchers

Under which criteria data/document could be used

No criteria was defined for access the data

From where data/document is obtainable

Dr.Mahboobeh Rashidi Dr.Mojtaba Ghorbi

What processes are involved for a request to access data/document

No processes were defined for access the data

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mojtaba Ghorbi

Position

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Trial results**Please tick if results have been published**

Yes

Summary result posting date

2021-06-08, 1400/03/18

Table of baseline comparisonURL: <http://mjiri.iums.ac.ir/article-1-7288-en.html>**Participant flow diagram**URL: <http://mjiri.iums.ac.ir/article-1-7288-en.html>**Table of variable outcomes' results**URL: <http://mjiri.iums.ac.ir/article-1-7288-en.html>**Table of adverse events**1URL: <http://mjiri.iums.ac.ir/article-1-7288-en.html>**First publication date**

2021-07-07, 1400/04/16

Abstract of published paper

Background and Objectives: N-acetylcysteine is an antioxidant derived from the amino acid cysteine and is one of the drugs used in the treatment of respiratory diseases. The aim of this study was to investigate the effect of N-acetylcysteine on the treatment of acute respiratory distress syndrome in mechanically ventilated patients admitted to the intensive care unit. **Methods:** This study was a randomized clinical trial. Patients under mechanical ventilation admitted to the intensive care unit were examined. Patients in the intervention group received 150 mg/kg of NAC drug internally. Intravenously received on the first day of hospitalization and then 50 mg/kg on the first to fourth days. Patients in the control group will receive routine care. The vital signs, level of consciousness of patients, and another important variable were recorded. Data were analyzed using statistical tests and SPSS software version 24. **Results:** There was no significant difference between MAP, heart rate, respiratory rate, O₂Sat, APACHE II score and pulmonary capacity of patients in the two groups on the first, second, third and fourth days after the intervention ($P>0.05$). There was no significant difference between level of consciousness (according to GCS criteria), respiratory index (PAO₂/FIO₂) and PEEP of patients in the two study groups within 1 to 2 days after the intervention ($P>0.05$). There was a significant difference between level of consciousness (based on GCS criteria), respiratory index (PAO₂/FIO₂) and PEEP of patients in the two study groups within 3 to 4 days after the intervention ($P<0.05$). There was no significant difference between the duration of hospitalization in the ICU, the time required for mechanical ventilation and the mortality rate of patients in the two groups ($P>0.05$). **Conclusion:** It seems that N-acetylcysteine has a positive effect on the treatment of acute respiratory distress syndrome in mechanically ventilated patients admitted to the intensive care unit.