Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 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 oneand therapy will contentious 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 vetilation -APACHEH II score -ICU length of stay -Duration of mechanical ventilation support - mortality rate and -FRC the parameter will record 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 ≥ 200 mmhg PEEP≥ 10 cm H2O Bilateral Pulmonary infiltrates on the chest x ray Exclusion ceriteria: atients 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 contentious 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 ≥ 200 mmhg PEEP≥ 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
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by simple randome method, after identifying eligible patients, they will be randomly assigned a tree-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,Khusestan, Iran
City
Ahvaz
Province
Khouzestan
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 contentious 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
Khouzestan
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
Khouzestan
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
Khouzestan
Postal code
6135715794
Phone
+98 41 3235 0348
Email
ghorbi.m@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mojtaba Ghorbi
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+98 41 3235 0348
Email
ghorbi.m@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
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Mojtaba Ghorbi
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+98 41 3235 0348
Email
ghorbi.m@ajums.ac.ir

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

Trial results

Please tick if results have been published
Yes
Summary result posting date
2021-06-08, 1400/03/18
Table of baseline comparison

URL: 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.