Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the effect of inhaled heparin in the treatment of patients with adult respiratory distress syndrome hospitalized in the intensive care unit

Protocol summary

Study aim

Investigation of the effect of inhaled heparin in the treatment of patients with adult respiratory distress syndrome

Design

In this study, 60 blind two-way ARDS intubation blind clinical trial trials were randomly divided into two groups of intervention and control.

Settings and conduct

In this study, 60 ARSD patients were selected as available in the ICU of Golestan Hospital in Ahvaz and were divided into two groups of intervention and control in a simple random manner. Patients of the intervention group, 5000 units of heparin in the nebulizer are inhaled every 12 hours for 7 days and used for patients of the normal saline control group. They were informed.

Participants/Inclusion and exclusion criteria

criteria include:Patients 18 to 60 years, Under mechanical ventilation for more than 48 hours, Respiratory index PAO2 / FIO2 ≤200 mmhg, Bilateral pulmonary infiltration in the chest x-ray, Lack of heart disease and previous lung disease Positive end expiratory pressure or PEEP≥ ventilator 5 cmh2, No history of intracerebral hemorrhage in the past 12 months and No history of heparin-induced thrombocytopenia. Non-entry criteria: Dissatisfaction to continue working on the study, Hypersensitivity to heparin, Uncontrolled bleeding or bleeding disorders, PTT and INR impaired and Patients receiving therapeutic doses of heparin, anaxaparin and warfarin.

Intervention groups

Patients of the intervention group, 5,000 units every 12 hours for 7 days and used for patients of normal saline control group. It is then connected to a ventilator.

Main outcome variables

In addition to vital signs and alertness levels, PAO2 / FIO2, ABG, Pao2, Pulmonary Shant Percentage, Sao2, PEEP, hospital stay time, time required for mechanical ventilation, 48-hour, 7-day mortality rate, and lung capacity of patients , Tidal Volume, Respiratory rate, Minute Ventilation, Paco2 were recorded during the 7-day study period.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190506043492N4**
Registration date: **2020-06-22, 1399/04/02**
Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**
Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Milad Arabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

arabi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-07-10, 1399/04/20

Actual recruitment start date
2020-04-08, 1399/01/20
Actual recruitment end date
2020-06-21, 1399/04/01
Trial completion date
2020-06-21, 1399/04/01

Scientific title
Investigation of the effect of inhaled heparin in the treatment of patients with adult respiratory distress syndrome hospitalized in the intensive care unit

Public title
Investigation of the effect of inhaled heparin in the treatment of patients with adult respiratory distress syndrome hospitalized in the intensive care unit
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18 to 60 years Under mechanical ventilation for more than 48 hours Respiratory index PAO2 / FIO2 ≤200 mmhg Bilateral pulmonary infiltration in the chest x-ray Lack of heart disease and previous lung disease Positive end expiratory pressure or PEEP≥ ventilator 5 cmh2 No history of intracerebral hemorrhage in the past 12 months No history of heparin-induced thrombocytopenia
Exclusion criteria:
Dissatisfaction to continue working on the study Hypersensitivity to heparin Uncontrolled bleeding or bleeding disorders PTT and INR impaired Patients receiving therapeutic doses of heparin, anaxaparin and warfarin
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly selected and divided into two groups of intervention (heparin recipient) and control (normal saline recipient) through a table of random numbers assigned to even numbers for the intervention group and individual numbers for the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the person who injected the drug was unaware that the syringe contained heparin or normal saline because the drug was taken by another anesthesiologist and stamped 1 and 2, and the person who took the blood sample for coagulation tests Patients were unaware of the type of intervention and the type of medication that had been injected for the patients. In this study, statistical analyzer was also unaware of the type of groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of ahvaz jundishapur University of Medical Sciences
Street address
Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357157941
Approval date
2020-04-25, 1399/02/06
Ethics committee reference number
IR.AJUMS.REC.1399.102

Health conditions studied

1

Description of health condition studied
Acute respiratory distress syndrome
ICD-10 code
J80
ICD-10 code description
Acute respiratory distress syndrome

Primary outcomes

1

Description
Respiratory index: PAO2 / FIO2
Timepoint
1 to 7 days after the intervention
Method of measurement
Ventilator

2

Description
Arterial blood gas parameters
Timepoint
1 to 7 days after the intervention
Method of measurement
ABG test

3

Description
The amount of PEEP required for effective mechanical ventilation
Timepoint
1 to 7 days after the intervention
Method of measurement
Ventilator

4

Description
The time required for mechanical ventilation
Timepoint
1 to 7 days after the intervention
Method of measurement
The number of days it has been subjected to mechanical ventilationnumber

5

Description
Mortality rate is 48 hours and 7 days
Timepoint
1 to 7 days after the intervention
Method of measurement
Mortality rate

6

Description
Respiratory parameters
Timepoint
1 to 7 days after the intervention
Method of measurement
Lung capacity، Tidal Volume, Respiratory rate, Minute Ventilation, Paco2

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group In addition to routine care, 5,000 units are used every 12 hours for 7 days.The heparin used is 5,000 units produced by Iran Pakhsh Broadcasting Company, which is diluted with 2 cc of distilled water and then poured into a nebulizer device and the nebulizer is connected to the chip pipe and the ventilator is connected.
Category
Treatment - Drugs

2

Description
Control group: In addition to routine care, patients in the control group poured 2 cc of normal saline into the nebulizer every 12 hours for 7 days, and the nebulizer was connected to the chip tube and then to the ventilator.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Nastaran sadat Hoseini
Street address
Golestan Hospital, Golestan Boulevard
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
eglantin92@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Vice Chancellor For Research of Ahvaz Jundishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
Shaker.z@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
Nastaran sadat Hoseini
Position
Associate Professor
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
Eglantin92@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Nastaran sadat Hoseini
Position
Associate Professor
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
Eglantin92@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Nastaran sadat Hoseini
Position
Associate Professor
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
Email
Eglantin92@gmail.com

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