

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 $PAO_2 / FIO_2 \leq 200$ mmhg, Bilateral pulmonary infiltration in the chest x-ray, Lack of heart disease and previous lung disease Positive end expiratory pressure or $PEEP \geq$ 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, PAO_2 / FIO_2 , ABG, Pao_2 , Pulmonary Shant Percentage, Sao_2 ,

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, $Paco_2$ 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)

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+98 61 3374 3001

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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 $PAO_2 / FIO_2 \leq 200$ mmhg Bilateral pulmonary infiltration in the chest x-ray Lack of heart disease and previous lung disease Positive end expiratory pressure or $PEEP \geq$ 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

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

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget 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: PAO_2 / FIO_2 **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 Paksh 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

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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

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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

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

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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