

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of nebulized heparin on days without ventilator in intensive care unit patients

#### Protocol summary

##### Study aim

Evaluation of the effect of nebulized heparin on days without ventilator in intensive care unit patients

##### Design

This study will be a clinical trial with a controlled double-blind randomized controlled group; randomized phase 3 will be analyzed on 75 randomized block patients using random numbers generated by SPSS 22 software.

##### Settings and conduct

In patients, the intensive care unit will be performed in Imam Khomeini Educational and Medical Center in Sari. To conduct the research, after obtaining the necessary permits and after obtaining the approval of the ethics committee and explaining the research to the patients and obtaining the patient's informed consent, they will be selected in the intensive care unit. Initial selection of patients according to the conditions of the research units.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients of both sexes and over 18 years of age required more than 2 hours for invasive mechanical ventilation and GCS above 9; patients with heparin sensitivity; Heparin-induced thrombocytopenia; history of pulmonary hemorrhage during the past three months, uncontrolled bleeding, or history of bleeding such as cerebral hemorrhage in the past year, and patients who had an epidural catheter or within 2 hours of catheterization.

##### Intervention groups

In the intervention group of heparin 5000 international units 1 ml (Caspian Supply, Tehran, Iran) will be prescribed. Patients will receive 5,000 units of heparin nebulizer every 6 hours for 7 days. Control group: Normal saline will be discontinued twice daily at 1 cc during this study for 7 days in the heparin group, but the control group will receive normal saline as usual.

##### Main outcome variables

Ventilator-free days will be among the surviving patients on day 28

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211010052718N2**

Registration date: **2022-05-19, 1401/02/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-19, 1401/02/29**

Update count: **0**

##### Registration date

2022-05-19, 1401/02/29

##### Registrant information

##### Name

alireza nikzad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3326 3539

##### Email address

a.nikzad@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-19, 1401/01/30

##### Expected recruitment end date

2022-05-21, 1401/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of nebulized heparin on days without ventilator in intensive care unit patients

## Public title

Evaluation of the effect of nebulized heparin on days without ventilator in intensive care unit patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients of both sexes and over 18 years old They needed more than 2 hours of aggressive mechanical ventilation GCS above 9 No underlying pulmonary problems

### Exclusion criteria:

Patients receiving therapeutic doses of heparin enoxaparin, warfarin or dabigatran during the study Uncontrolled bleeding or a history of bleeding such as cerebral hemorrhage in the past year and patients who had an epidural catheter or were implanted within 2 hours of hospitalization. Patients with heparin sensitivity

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **74**

## Randomization (investigator's opinion)

Randomized

## Randomization description

A random block-making list will be created using randomly generated computer-generated numbers. Patients will be randomly divided into two groups: nebulized heparin or normal saline using block grade four. A random blocking list will be created using random numbers generated by the computer. Patients, physicians, test staff, and outcome evaluators will be blinded to group assignments.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients, physicians, test staff, and outcome evaluators will be blinded to group assignments. According to the questionnaire, patients are divided into two groups A and B and these two substances (heparin and normal saline) are delivered in two syringes at a rate of 1 cc that has been prepared in advance to the ward nurse. And the nurse does not know the type of substance. Finally, the data will be analyzed with SPSS 22 software.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Khomeini Hospital, Sari Imam University of Medical Sciences

##### Street address

Amir Mazandarani Blvd. Imam Khomeini Hospital

##### City

Sari

##### Province

Mazandaran

##### Postal code

33131 - 48166

#### Approval date

2022-03-16, 1400/12/25

#### Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1401.004

## Health conditions studied

### 1

#### Description of health condition studied

Acute respiratory distress syndrom

#### ICD-10 code

J68.3

#### ICD-10 code description

Other acute and subacute respiratory conditions due to chemicals, gases, fumes and vapors

## Primary outcomes

### 1

#### Description

Improve oxygenation

#### Timepoint

After starting the intervention on a daily basis for 15 days

#### Method of measurement

Arterial blood sampling device

## Secondary outcomes

### 1

#### Description

Compliance

#### Timepoint

After starting the intervention on a daily basis for 15 days

**Method of measurement**

Ventilator

**Intervention groups****1****Description**

Intervention group:Heparin 0. . . international unit 1 ml(Caspian Supply, Tehran, Iran)Will be prescribedPatients for 7 days heparin nebulizer at a dose of 5000 unitsThey will receive it every 6 hours

**Category**

Treatment - Drugs

**2****Description**

Control group: Normal saline will be discontinued twice daily at1 cc during this study for 7 days in the heparin group, but the control group will receive normal saline as usual.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Medical Center

**Full name of responsible person**

Alireza Nikzad

**Street address**

Amir Mazandarani Blvd.

**City**

Sari

**Province**

Mazandaran

**Postal code**

33131 - 48166

**Phone**

+98 11 3336 1700

**Fax**

+98 11 3336 1700

**Email**

A.NIKZAD@MAZUMS.AC

**Web page address**<http://mazums.ac.ir>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saedi

**Street address**

Moalem Ave

**City**

Sari

**Province**

Mazandaran

**Postal code**

48157-33971

**Phone**

+98 11 3325 7230

**Fax**

+98 11 3325 7230

**Email**

m.saedi@mazums.ac.ir

**Web page address**<https://www.mazums.ac.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Alireza Nikzad

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Email**

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**Web page address**<http://mazums.ac.ir>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Alireza Nikzad

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Mazandaran University of Medical Sciences

**Full name of responsible person**

Alireza Nikzad

**Position**

Associate professor

**Latest degree**

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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