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 units1 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)

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+98 11 3326 3539

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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 ۵۰۰۰ 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
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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
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48157-33971
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Fax
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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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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