

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of Daily Administration of Nebulized Heparin on Prevention of Endotracheal Tube Blockage by Clot and Mucus Plug Compared to Normal Saline in Patients with Pneumonia

Protocol summary

Study aim

Effect of daily administration of nebulized heparin on prevention of endotracheal tube blockage by clot and mucus plug in patients with pneumonia

Design

This study was double blind clinical trial with parallel groups that using randomized block method and available sampling was performed among patients admitted in the ICU in two groups of intervention and control and the sample size in each group was 20 patients.

Settings and conduct

This Study Is Performed on 40 Patients with Pneumonia who Have Been Intubated and Admitted to the ICU of Imam Khomeini Hospital in Ahvaz. Patients Are Randomly Divided into Two Groups of 20 Patients. Patients with Inclusion Criteria After Randomization Procedures Receive Heparin Ampoules of 5000 Units per 1 MI Mixed In 4 Cc Of Normal Saline 0.9% every 6 Hours as Nebulization through the Endotracheal Tube. This is done daily for up to 14 days. In the Same Way and in the Same amount in the Same Syringe, Which Is Distilled Water, We Nebulize the Patient in the Control Group

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with pneumonia who have been intubated and admitted to the ICU. Patients must have an apache score of less than 25. Exclusion Criteria: Thrombocytopenia or a history of heparin-induced thrombocytopenia, Coagulation disorder with INR above 1.5 pregnant women, Any active bleeding and history of intracranial hemorrhage during the last 3 months

Intervention groups

The intervention group in our study includes patients who receive nebulized heparin. The control group in our study includes patients who receive a placebo that is normal saline

Main outcome variables

The degree of obstruction of the endotracheal tube by plug or bare mucus; Hypoxia; Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200821048470N1**

Registration date: **2020-10-12, 1399/07/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-12, 1399/07/21**

Update count: **0**

Registration date

2020-10-12, 1399/07/21

Registrant information

Name

Houshmand Hosseinienezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 7410

Email address

hosseinienezhad.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-06, 1399/07/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Daily Administration of Nebulized Heparin on Prevention of Endotracheal Tube Blockage by Clot and Mucus Plug Compared to Normal Saline in Patients with Pneumonia

Public title
"Effect of Nebulized Heparin in Patients with Pneumonia"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with pneumonia who have been intubated and admitted to the ICU. All patients have an apache score less than 25.
Exclusion criteria:
 Thrombocytopenia or a history of heparin-induced thrombocytopenia Coagulation disorder with INR above 1.5 pregnant women Any active bleeding and history of intracranial hemorrhage during the last 3 months
 Patients receiving anticoagulants

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Out of 40 Patients who Entered the Study by Random Block Method, Individuals are Randomly Assigned to Both Interventional and Non-interventional Groups (with placebo). Randomized numbers from 1 to 40 was produced with a calculator, the first twenty numbers allocated to intervention group and the other twenty numbers allocated to control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Once the patients in the study groups have been identified, the drug and placebo are placed in the same syringes as they are in appearance, and thus patients will not be informed of the contents inside it.

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

Jundishapur University of Medical Sciences, Golestan Blvd., Golestan Town

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-02-19, 1398/11/30

Ethics committee reference number

IR.AJUMS.REC.1399.257

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J95.851

ICD-10 code description

Ventilator associated pneumonia

Primary outcomes

1

Description

The degree of obstruction of the endotracheal tube by plug or bare mucus

Timepoint

On admission and daily

Method of measurement

Clinical Information Collection Form

2

Description

Hypoxia

Timepoint

On admission and daily

Method of measurement

Drop in arterial blood oxygen saturation to less than 90 or more than 4% of basal level after elimination of other common causes

3

Description

Infection

Timepoint

On admission and daily

Method of measurement

New VAP event based on different clinic or graph with primary lung infection

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group, patients receive 5,000 units of heparin ampoules per 1 ml mixed with 4 cc of 0.9% normal saline every 6 hours as a nebulization through a tracheal tube. This is done daily for up to 14 days or until the patient becomes extubate or dies.

Category

Treatment - Drugs

2

Description

Control group: in this group, patients after randomization, receive 5 cc of normal saline 0.9% through endotracheal tube nebulization every 6 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Hooshmand Hosseinienezhad

Street address

Imam Khomeini Hospital., Azadegan Ave

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Ahvaz

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6193673166

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+98 61 3221 5574

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Jundishapur University of Medical Sciences,
Chancellor for Research and Technology
Development, Golestan Blvd., Golestan Town

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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

Hooshmand Hosseinienezhad

Position

Pulmonary fellowship

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Seyed Hamid Borsi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Hooshmand Hosseinienezhad

Position
Fellowship (sub-specialist assistant)

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic Data and the Result of Clinical Trial

When the data will become available and for how long

access begins one year after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Research on related issues

From where data/document is obtainable

Houshmand Hosseinienezhad

What processes are involved for a request to access data/document

Communicate with the responsible person via Email

Comments