

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Study of the effect of inhaled heparin on duration of antibiotic therapy in patients with ventilator associated pneumonia

Protocol summary

Study aim

Determination of the effect of inhaled heparin on the reduction of the duration of antibiotic therapy based on clinical pulmonary infection severity score (CPIS) and the serum level of pro-calcitonin in patients of our study.

Design

This study was single 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 21 patients.

Settings and conduct

After identifying the intervention and control groups and after the randomization process in the hospital's intensive care unit, 2 ml of the heparin injected into the 2-cc syringe is drawn into the nebulizer in the patient's intervention group. In the same way and in the same syringe, placebo which is distilled water, is drawn into the nebulizer in the control group. Standard treatment is continued in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients on the basis of CPIS ≥ 6 suspected with ventilator associated pneumoniae and age above 18 years of age. Exclusion criteria: Patients who on mechanical ventilation < 48 h, cancer patients, chronic immune deficiency / chronic infections / concurrent infections at other sites / Do not resuscitate patients renal replacement therapy, heparin or Low molecular weight heparin or other anticoagulants, having an Body mass index > 40 , having a history of heparin allergy or a history of Heparin induced thrombocytopenia, history of bleeding in the past 3 months, or hemorrhagic disorders, intra cranial hemorrhage over the last year

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 distilled water

Main outcome variables

Duration of antibiotic treatment; procalcitonin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140310016917N8**

Registration date: **2019-07-11, 1398/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-11, 1398/04/20**

Update count: **0**

Registration date

2019-07-11, 1398/04/20

Registrant information

Name

Ali Ashraf

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1321 0434

Email address

alishraf@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study of the effect of inhaled heparin on duration of antibiotic therapy in patients with ventilator associated pneumonia

Public title
Inhaled heparin in pneumonia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients are included in the study according to the score of the severity of pulmonary infection index (>=6) and age above 18 years old.
Exclusion criteria:
Mechanical ventilation less than 48 h during hospitalization
Cancer and immunodeficient patients
chronic infection and coinfection in other sites of body
Do not resuscitate patients
CRRT dependency
Therapeutic dose of any anticoagulants
BMI>40
History of allergy to heparin and HIT
History of bleeding in 3 month ago and bleeding tendency
ICH in 1year ago
possibility of epidural catheter insertion during next 48 h

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**
More than 1 sample in each individual
Number of samples in each individual: **2**
A blood sample to examine the relevant parameters and a sample of tracheal secretions for culture and antibiogram

Randomization (investigator's opinion)
Randomized

Randomization description
Out of 42 subjects who entered the study by random block method, Individuals are randomly assigned to both interventional and non-interventional groups (with placebo) by statistical random generator software.

Blinding (investigator's opinion)
Single blinded

Blinding description
Once the subjects 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 Guilan University of Medical Sciences
Street address
Namjoo street
City
Rasht
Province
Guilan
Postal code
4193893345

Approval date
2019-05-29, 1398/03/08

Ethics committee reference number
IR.GUMS.REC.1398.117

Health conditions studied

1

Description of health condition studied
VENTILATOR ASSOCIATED PNEUMONIA(VAP)

ICD-10 code
J95.851

ICD-10 code description
Ventilator associated pneumonia

Primary outcomes

1

Description
Duration of antibiotic therapy

Timepoint
Every other day, procalcitonin is measured to determine the length of antibiotic treatment

Method of measurement
Procalcitonin Measuring Kit

Secondary outcomes

1

Description
Clinical pulmonary infection severity score

Timepoint
On admission and daily

Method of measurement

Clinical Information Collection Form

2

Description

C Reactive Protein

Timepoint

On admission then daily

Method of measurement

Clinical Information Collection Form

3

Description

Sepsis Organ Failure Assessment score

Timepoint

On admission then daily

Method of measurement

Clinical Information Collection Form

4

Description

Acute Physiologic And Chronic Health Evaluation II score

Timepoint

on admision then daily

Method of measurement

Clinical Information Collection Form

Intervention groups

1

Description

Intervention group: after appropriate randomization drug (nebulized heparin in this group) in dose of 2 cc (10,000 heparin units) every 4 hours is given through a jet nebulizer located 30 cm in the tracheal tube at the inspiratory arm of ventilator. Other measures will be exactly the same as the recipients of standard pneumonia treatment (control group). The Heparin ampoule is supplied by the Caspian Company and is at 5000 units per cc.

Category

Treatment - Drugs

2

Description

Control group: after appropriate randomization drug (distilled water in this group) in dose of 2 cc every 4 hours is given through a jet nebulizer located 30 cm in the tracheal tube at the inspiratory arm of ventilator and standard treatment consistent of antibiotics in appropriate for the local prevalency in the ICU initially was started and then continued on the basis of culture of pulmonary secretions until the pro calcitonin serum level is in the non infected stage or at most 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Ali Ashraf

Street address

17- Shahrivar Street

City

Rasht

Province

Guilan

Postal code

4193893345

Phone

+98 13 3322 5242

Email

Draliashrاف@yahoo.fr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

Street address

Shahid beheshti Highway

City

Rasht

Province

Guilan

Postal code

4144666949

Phone

+98 13 3333 5821

Fax

+98 13 3333 6395

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Guilan University of Medical Sciences

Proportion provided by this source

1

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Mostafa Saeedinia
Position
Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Poursina hospital
City
Rasht
Province
Guilan
Postal code
4139638459
Phone
+98 13 1321 0434
Fax
+98 13 1324 5132
Email
mostafa.saeedinia@gmail.com
Web page address
<http://www.arc.gums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Ali Ashraf
Position
Assistan professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Namjoo Street
City
Rasht
Province
Guilan

Postal code
4193713194
Phone
+98 13 1321 0434
Fax
Email
aliashraf@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Ali Ashraf
Position
Assistan professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Namjoo Street
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 1321 0434
Fax
Email
aliashraf@gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To protect the secrets of patients and to observe ethics of study

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available