

# 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 21patients.

##### 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 $\geq$ 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 Hparin 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