

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Evaluation of nebulized heparin efficacy in pediatric patients with acute respiratory distress syndrome

#### Protocol summary

##### Study aim

Evaluation of heparin nebulize efficacy in the treatment in pediatric patients with Acute Respiratory Distress Syndrome

##### Design

The clinical trial with a control, parallel group, double-blinded, randomize, in third clinical phase on 66 patients . Six Block Random Permutation and Microsioft Excel 2010 software will be used randomization.

##### Settings and conduct

Since the participants in this research are children under the age of 18, they will not know about how they will be placed in treatment groups, due to the age limit. Also, due to the impossibility of making a placebo, a person outside of the research group will be responsible for injecting the drug, and this person has no interference in collecting and analyzing data. In addition, the people who are responsible for collecting and analyzing information will not have any information about how patients are placed in these groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 1 month to 18 years  
Patients with respiratory distress syndrome  
Exclusion criteria: History of any bleeding disorders  
Uncontrolled active bleeding

##### Intervention groups

In two groups, patients receive their main medicine. In placebo group, distilled water nebulizer is used with dose of 0.5 milliliter per kilogram of body weight every 12 hours. In intervention group, heparin nebulizer is used with 100 unit per kilogram of body weight every 12 hours for seven days. All the patients respiratory information like Fio2/Pao2 and the respiratory indices will be recorded at the certain time ten minutes before the ventilator is changed and patients position.

##### Main outcome variables

Respiratory Syndrome Severity: ventilation days need

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230724058907N1**

Registration date: **2023-12-11, 1402/09/20**

Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**

Update count: **0**

##### Registration date

2023-12-11, 1402/09/20

##### Registrant information

##### Name

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##### Name of organization / entity

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Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-12-22, 1402/10/01

##### Expected recruitment end date

2024-10-21, 1403/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                   |                                                                                               |
|---------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Evaluation of nebulized heparin efficacy in pediatric patients with acute respiratory distress syndrome |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | water nebulize) groups. It will be done completely randomly by a person outside the research team who has no interference in the collection and analysis of data. |                                                                                               |
| <b>Public title</b>                                                                                     | Evaluation of nebulized heparin efficacy in acute respiratory distress syndrome                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Placebo</b>                                                                                                                                                    | Used                                                                                          |
| <b>Purpose</b>                                                                                          | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Assignment</b>                                                                                                                                                 | Parallel                                                                                      |
| <b>Inclusion/Exclusion criteria</b>                                                                     | <p><b>Inclusion criteria:</b><br/>Children older than one month to 18 years old<br/>The underlying disease of acute respiratory distress syndrome<br/>Patients under mechanical ventilation for more than 48 hours with Pao<sub>2</sub>/Fio<sub>2</sub>&lt;300<br/>Patients who are expected to undergo invasive ventilation in the next 24 hours<br/>In CXR, bilateral pulmonary infiltration can be seen (5cmH<sub>2</sub>O PEEP&gt;)</p> <p><b>Exclusion criteria:</b><br/>History of allergy to heparin<br/>Bleeding history in the last 3 months<br/>History of any bleeding and coagulation disorders<br/>History of cerebral hemorrhage in the last year<br/>Uncontrolled active bleeding<br/>Simultaneous use of antiplatelet, anticoagulant and thrombolytic drugs<br/>Unwillingness to participate in the study</p> | <b>Other design features</b>                                                                                                                                      |                                                                                               |
| <b>Age</b>                                                                                              | From <b>1 month</b> old to <b>18 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Secondary Ids</b>                                                                                                                                              | empty                                                                                         |
| <b>Gender</b>                                                                                           | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Ethics committees</b>                                                                                                                                          |                                                                                               |
| <b>Phase</b>                                                                                            | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>1</b>                                                                                                                                                          |                                                                                               |
| <b>Groups that have been masked</b>                                                                     | <ul style="list-style-type: none"> <li>Participant</li> <li>Investigator</li> <li>Outcome assessor</li> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Ethics committee</b>                                                                                                                                           |                                                                                               |
| <b>Sample size</b>                                                                                      | Target sample size: <b>66</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Name of ethics committee</b>                                                                                                                                   | Ethics committee of Ahvaz University of Medical Sciences                                      |
| <b>Randomization (investigator's opinion)</b>                                                           | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Street address</b>                                                                                                                                             | Ground floor, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz , Iran. |
| <b>Randomization description</b>                                                                        | In this part "www.sealedenvelope.com" will be used to create random blocks to assign patients into groups and as a result a sequence of four blocks will be made. Considering that we have two groups in this study, our blocks of four can be as follows: AABB, ABAB, BABA, BBAA, BAAB, ABBA where A and B represent our groups. Then these six blocks will be numbered, and samples will be taken from these six blocks by replacement method. These blocks will then be put together to form our randomization sequence.                                                                                                                                                                                                                                                                                                   | <b>City</b>                                                                                                                                                       | Ahvaz                                                                                         |
| <b>Blinding (investigator's opinion)</b>                                                                | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Province</b>                                                                                                                                                   | Khouzestan                                                                                    |
| <b>Blinding description</b>                                                                             | The study will be done in a double-blind method. Neither the patient nor the doctor know how to be placed in the groups. To consider the age of the patients and the usual condition of consciousness in the ICU, it can be claimed none of them are aware of the drugs they are receiving. Because of the impossibility of making a placebo, this study will be done in a double blind manner in two intervention ( heparin nebulize) and placebo (Distilled                                                                                                                                                                                                                                                                                                                                                                 | <b>Postal code</b>                                                                                                                                                | 15794-61357                                                                                   |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Approval date</b>                                                                                                                                              | 2023-07-15, 1402/04/24                                                                        |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Ethics committee reference number</b>                                                                                                                          | IR.AJUMS.REC.1402.247                                                                         |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Health conditions studied</b>                                                                                                                                  |                                                                                               |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>1</b>                                                                                                                                                          |                                                                                               |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Description of health condition studied</b>                                                                                                                    | Acute respiratory distress syndrome                                                           |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>ICD-10 code</b>                                                                                                                                                | J80                                                                                           |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>ICD-10 code description</b>                                                                                                                                    | Acute respiratory distress syndrome                                                           |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Primary outcomes</b>                                                                                                                                           |                                                                                               |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>1</b>                                                                                                                                                          |                                                                                               |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Description</b>                                                                                                                                                | Severity of acute respiratory distress syndrome                                               |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Timepoint</b>                                                                                                                                                  | Time to enter the study or 0, 3, 5 and 7 days                                                 |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Method of measurement</b>                                                                                                                                      | Pediatric acute respiratory distress syndrome criteria                                        |
|                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Secondary outcomes</b>                                                                                                                                         |                                                                                               |

## 1

### **Description**

Oxygen saturation with pulse oximetry to fraction of inspired oxygen ratio

### **Timepoint**

Time to enter the study or 0, 3, 5 and 7 days

### **Method of measurement**

Pulse oximetry and mechanical ventilator

## 2

### **Description**

Arterial oxygen pressure by arterial blood gas to fraction of inspired oxygen ratio

### **Timepoint**

Time to enter the study or 0, 3, 5 and 7 days

### **Method of measurement**

Blood sample and mechanical ventilator

## 3

### **Description**

Oxygen saturation index ( fraction of inspired oxygen \*mean airway pressure\*100 ) to oxygen saturation by pulse oximetry ratio

### **Timepoint**

Time to enter the study or 0, 3, 5 and 7 days

### **Method of measurement**

Pulse oximetry and mechanical ventilator

## 4

### **Description**

Oxygenation index (fraction of inspired oxygen \*mean airway pressure\*100) to oxygen saturation by arterial blood gas ratio

### **Timepoint**

Time to enter the study or 0, 3, 5 and 7 days

### **Method of measurement**

Blood sample and mechanical ventilator

## 5

### **Description**

Number of days required mechanical ventilation

### **Timepoint**

Time to enter the study to discharge

### **Method of measurement**

Patient file

## 6

### **Description**

Length of stay in Intensive Care Unit

### **Timepoint**

Time to enter the study to discharge

### **Method of measurement**

Patient file

## 7

### **Description**

Adverse effect

### **Timepoint**

Full time of study

### **Method of measurement**

Patient file and tests

## **Intervention groups**

## 1

### **Description**

Intervention group with nebulized heparin 5000 unit per 1 milliliter Sina darou (preservative free) with dose100 Unit per kilogram of body weight every 12hours for 7 days

### **Category**

Treatment - Drugs

## 2

### **Description**

Control or placebo group with nebulized distilled water Caspian company 0.5 milliliter per kilogram of body weight every 12hours for 7 days

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Abuzar hospital

#### **Full name of responsible person**

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## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Ahvaz University of Medical Sciences

#### **Full name of responsible person**

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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**  
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## Person responsible for updating data

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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