

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

Fatemeh Minagar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4244 2249

Email address

minagar.f@ajums.ac.ir

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.	
Public title	Evaluation of nebulized heparin efficacy in acute respiratory distress syndrome	Placebo	Used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Children older than one month to 18 years old The underlying disease of acute respiratory distress syndrome Patients under mechanical ventilation for more than 48 hours with Pao₂/Fio₂<300 Patients who are expected to undergo invasive ventilation in the next 24 hours In CXR, bilateral pulmonary infiltration can be seen (5cmH₂O PEEP>) Exclusion criteria: History of allergy to heparin Bleeding history in the last 3 months History of any bleeding and coagulation disorders History of cerebral hemorrhage in the last year Uncontrolled active bleeding Simultaneous use of antiplatelet, anticoagulant and thrombolytic drugs Unwillingness to participate in the study	Other design features	
Age	From 1 month old to 18 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	3	1	
Groups that have been masked	- Participant - Investigator - Outcome assessor - Data analyser	Ethics committee	
Sample size	Target sample size: 66	Name of ethics committee	Ethics committee of Ahvaz University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Ground floor, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz , Iran.
Randomization description	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.	City	Ahvaz
Blinding (investigator's opinion)	Double blinded	Province	Khouzestan
Blinding description	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	Postal code	15794-61357
		Approval date	2023-07-15, 1402/04/24
		Ethics committee reference number	IR.AJUMS.REC.1402.247
		Health conditions studied	
		1	
		Description of health condition studied	Acute respiratory distress syndrome
		ICD-10 code	J80
		ICD-10 code description	Acute respiratory distress syndrome
		Primary outcomes	
		1	
		Description	Severity of acute respiratory distress syndrome
		Timepoint	Time to enter the study or 0, 3, 5 and 7 days
		Method of measurement	Pediatric acute respiratory distress syndrome criteria
		Secondary outcomes	

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

Farzaneh hematian

Street address

Parastar (Tohid) Ave., Chahrshir, Ahvaz, Khozestan, Iran

City

Ahvaz

Province

Khouzestan

Postal code

6163614175

Phone

+98 61 3337 8311

Email

aboozar-hos@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Jundishapour University of medical Sciences, Esfand Ave., Golestan Blvd., Ahvaz, Iran

City

Ahvaz
Province
 Khouzeestan
Postal code
 6135715794
Phone
 +98 61 3311 0000
Email
 zakerkish-m@ajums.ac.ir
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
 Farzaneh Hematian
Position
 Associate Professor
Latest degree
 Specialist
Other areas of specialty/work
 Medical Pharmacy
Street address
 Abuzar Children's Educational and Therapeutic Hospital, Ahvaz
City
 Ahvaz
Province
 Khouzeestan
Postal code
 61635931
Phone
 +98 61 3444 9003
Email
 minagarfatima@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Ahvaz University of Medical Sciences
Full name of responsible person

Farzaneh Hematian
Position
 Associate professor
Latest degree
 Specialist
Other areas of specialty/work
 Medical Pharmacy
Street address
 Parastar (Tohid) Ave., Chahrshir, Ahvaz, Khozestan, Iran
City
 Ahvaz
Province
 Khouzeestan
Postal code
 6163614175
Phone
 +98 61 3444 9003
Email
 farzanehematian@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
 Ahvaz University of Medical Sciences
Full name of responsible person
 Fatemeh Minagar
Position
 Student
Latest degree
 A Level or less
Other areas of specialty/work
 Medical Pharmacy
Street address
 Pharmacy faculty , Ahvaz Jundishapur University of Medical Sciences, Golestan St. , Ahvaz , Iran.
City
 Ahvaz
Province
 Khouzeestan
Postal code
 6163614175
Phone
 +98 61 3444 9003
Email
 minagar.f@ajums.ac.ir

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