

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of endotracheal administration of N-acetylcysteine and heparin on symptom improvement in acute respiratory distress syndrome and lung contusion

Protocol summary

Study aim

Determination of the Effect of Intracerebellar N-acetylcysteine and Heparin on the Improvement of Symptoms of Acute Respiratory Syndrome and Lung contusion

Design

In clinical trial phase 3, single blind, random allocation. 104 patients with inclusion criteria are divided into two groups. The first group receive only ICU routine treatments with 10 millilitr saline and the control group receive 500 units of heparin every four hours and 200 mg of acetylcysteine Soluble in 10 millilitr every 4 hours by intratracheal.

Settings and conduct

Clinical trial study; Hajar Hospital, single blind and blindness of the research is from the side of the investigator and the investigator does not know the type of drug used for the patient

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with Acute Respiratory Distress Syndrome and lung contusion
Exclusion criteria: pregnancy; allergy to heparin or acetylcysteine; active bleeding

Intervention groups

The first group receive only ICU routine treatments with 10 millilitr saline every 4 hours 1 times in the form of intratracheal injection and the control group receive 500 units of heparin every four hours and 200 mg of acetylcysteine Soluble in 10 millilitr saline every 4 hours by intratracheal.

Main outcome variables

Improvement of respiratory signs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190205042631N1**

Registration date: **2019-02-28, 1397/12/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-28, 1397/12/09**

Update count: **0**

Registration date

2019-02-28, 1397/12/09

Registrant information

Name

Hamid Roohi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 8891

Email address

hamidroohi123@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

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

The effect of endotracheal administration of N-acetylcysteine and heparin on symptom improvement in

acute respiratory distress syndrome and lung contusion		Postal code 8818718765
Public title The effect of endotracheal administration of N-acetylcysteine and heparin on symptom improvement in acute respiratory distress		Approval date 2017-07-22, 1396/04/31
Purpose Treatment		Ethics committee reference number 182.IR.SKUMS.REC.1396
Inclusion/Exclusion criteria Inclusion criteria: Patients with acute respiratory distress syndrome and lung contusion Exclusion criteria: Pregnancy Allergy to heparin or acetylcysteine Active bleeding		Health conditions studied 1 Description of health condition studied lung disorder ICD-10 code J98.9 ICD-10 code description Respiratory disorder, unspecified
Age From 18 years old to 70 years old		Primary outcomes 1 Description Improvement of respiratory symptoms. Timepoint After seven days Method of measurement Checklist
Gender Both		Secondary outcomes empty
Phase 3		Intervention groups 1 Description Intervention group: receive 500 units of heparin every four hours and 200 mg of acetylcysteine dissolved in 10 millilitr every 4 hours by intratracheal for 7days. Category Treatment - Drugs
Groups that have been masked • Participant • Investigator		2 Description Control group: receive only ICU routine treatments with 10 millilitr saline every 4 hours 1 times in the form of intratracheal injection for 7days. Category Treatment - Drugs
Sample size Target sample size: 26		Recruitment centers 1 Recruitment center Name of recruitment center Hajar hospital Full name of responsible person Hamid Rouhi
Randomization (investigator's opinion) N/A		
Randomization description		
Blinding (investigator's opinion) Single blinded		
Blinding description The blindness of the research is from the side of the investigator and the investigator does not know the type of drug used for the patient		
Placebo Not used		
Assignment Parallel		
Other design features		
Secondary Ids empty		
Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Shahrekord University of Medical Sciences Street address Vice Chancellor of Research and Technology , Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord,Iran City shahrekord Province Chahar-Mahal-va-Bakhtiari		

Street address

Hajar Hospital of Shahrekord University of Medical Sciences, ParastarAvenue,Shahrekord, Iran

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8819819854

Phone

+98 38 3222 0016

Email

hamidroohi@skums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor of Research and Technology
Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Kamal Solati

Street address

Vice Chancellor of Research and Technology
Shahrekord University of Medical Sciences, Kashani
Blvd, Shahrekord,Iran

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

881954525

Phone

+98 38 3334 2414

Email

solati@skums.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 of Research and Technology Shahrekord
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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Hamid Rouhi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Hajar Hospital of Shahrekord University of Medical Sciences, ParastarAvenue,Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718761

Phone

+98 38 3222 0016

Email

hamidroohi@skums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Hamid Rouhi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Hajar Hospital of Shahrekord University of Medical Sciences, ParastarAvenue,Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718758

Phone

+98 0383220016

Email

hamidroohi@skums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Hamid Rouhi

Position

Hajar Hospital of Shahrekord University of Medical Sciences, ParastarAvenue,Shahrekord, Iran

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Hajar Hospital of Shahrekord University of Medical Sciences, Parastar Avenue, Shahrekord, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718758

Phone

+98 38 3222 0016

Email

hamidroohi@skums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

No - There is not 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

Title and more details about the data/document

checklist information

When the data will become available and for how long

7 days

To whom data/document is available

En Researchers working in academia and academia

Under which criteria data/document could be used

article

From where data/document is obtainable

journals

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

publication of article

Comments