Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparing the efficacy of intrapleural injection of alteplase with intrapleural infusion of normal saline through a chest tube in patients with parapneumonic effusion requiring drainage referred to Akbar Hospital

Protocol summary

Study aim

Comparison of the effectiveness of intrapleural alteplase injection with intrapleural normal saline injection via chest tube in patients with parapneumonic effusion requiring drainage

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 30 patients. The rand function of Excel software was used for randomization. The control group will receive normal saline, and the intervention group will receive plasminogen activator at a dose of 0.1 mg/kg body weight, administered into the pleural space three times every 8 hours for 3 days.

Settings and conduct

This study will be conducted at Akbar Children's Hospital in Mashhad. All patients with empyema will be visited by a pediatric specialist and randomly assigned to the intervention and control groups. Allocation concealment will be performed using sealed envelopes. The present study is double-blind, in which patients and the patient outcome assessor are unaware of the patient grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pneumonia; effusion; (septa/loculation on US/paracentesis). Effusion: LDH>1000 or sugar<40 or Gram stain; or pus. Exclusion criteria: Bleeding/disorder or pneumothorax or persistent leak; or fistula.

Intervention groups

The control group will receive normal saline, and the intervention group will receive plasminogen activator at a dose of 0.1 mg per kilogram of body weight, injected into the pleural space three times every eight hours for three days.

Main outcome variables

1- Days elapsed until fever resolution and respiratory distress improvement 2- Duration of need for intravenous antibiotics 3- Need for thoracotomy or VATS 4- Laboratory criteria of inflammation ESR-CRP-CBCdiff

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250507065631N1**
Registration date: **2025-08-02, 1404/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-02, 1404/05/11**
Update count: **0**

Registration date

2025-08-02, 1404/05/11

Registrant information

Name

Parisan Omidvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3521 5860

Email address

pari.san68124@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-01, 1404/05/10

Expected recruitment end date

2025-10-02, 1404/07/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparing the efficacy of intrapleural injection of alteplase with intrapleural infusion of normal saline through a chest tube in patients with parapneumonic effusion requiring drainage referred to Akbar Hospital

Public title
Comparing the effectiveness of intrapleural alteplase injection with intrapleural normal saline injection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of pneumonia Pleural effusion
Exclusion criteria:
Evidence of bleeding or bleeding disorder Pneumothorax Persistent leak from chest tube site Evidence of bronchopleural fistula Evidence of fibrinous septa and loculation on ultrasound or pleural paracentesis results with any of the following: lactate dehydrogenase greater than 1000, glucose less than 40, Gram stain fails to identify organism, frank pus
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Using random allocation software, a list of random blocks with variable sizes of 4 and 6 is designed, each block containing an equal number of groups, and a number is assigned to each block. The order of the contents of each group ensures a balanced allocation of individuals in the study groups. When each patient visits, one of the blocks is randomly selected and the patient is assigned to one of the groups according to the order of its contents.
Blinding (investigator's opinion)
Double blinded
Blinding description
1. Blinding of participants - Both types of drugs (intrapleural alteplase and intrapleural normal saline) are provided in identical containers (same brand, color, shape, and packaging). - Labels are marked only with random codes (e.g., A or B) and do not indicate the type of drug. - If the drugs have a different taste/smell, a neutral flavoring/color is used so that they are not distinguishable. 2. Blinding of investigators (drug prescribing team) - The research team does not have access to the randomization list (this list is managed by a pharmacist or a central system outside the team). - The drugs are pre-coded, and the investigator only gives the code (e.g., vial “A”) to the patient without knowing the contents. - In case of complications, reports are recorded without mentioning the treatment group. 3. Blinding of outcome assessors (data analysis team) - Samples are sent to the laboratory with numerical codes (not A/B). - The evaluators do not know which treatment group each sample belongs to.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Medicine, Mashhad University of Medical Sciences
Street address
Central Organization of Mashhad University of Medical Sciences, Knowledge and Health Town, between Al-Shahidi Square and Shahid Javan Square, end of Shahid Fakuri Boulevard, Mashhad, Khorasan Razavi
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2025-04-08, 1404/01/19
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1404.031

Health conditions studied

1

Description of health condition studied
Abscess of lung and mediastinum
ICD-10 code
J85
ICD-10 code description
Abscess of lung and mediastinum

Primary outcomes

1

Description
Recovery
Timepoint

After the intervention is completed

Method of measurement

Monitoring vital signs with a vital signs monitor, thermometer, blood pressure monitor, and pulse oximeter

Secondary outcomes

1

Description

Erythrocyte sedimentation rate

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Erythrocyte sedimentation rate test

2

Description

CRP (C-reactive protein) test

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

It is performed using nephelometric or turbidometric methods in automated laboratory devices.

3

Description

CBC diff test (complete blood count with differential)

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Blood cell counting is performed using automated machines.

4

Description

Need for thoracotomy (open surgery) orminimally invasive surgery

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Imaging

5

Description

Fever

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Thermometer

6

Description

Respiratory distress

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Stopwatch

7

Description

Oxygen level

Timepoint

Before the intervention begins and after the intervention ends

Method of measurement

Pulse oximetry

Intervention groups

1

Description

Intervention group: In patients in the intervention group, plasminogen (TPA), produced by Samen Pharmaceutical Company, will be injected into the pleural space at a dose of 0.1 mg per kilogram of weight, 3 times every eight hours for three days.

Category

Treatment - Drugs

2

Description

Control group: In the control group, normal saline, produced by Samen Pharmaceutical Company, will be injected into the pleural space at a rate of 0.1 mg per kilogram of weight, 3 times every eight hours for three days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Children's Superspecialty Hospital

Full name of responsible person

Parisan Omidvar

Street address

Opposite Shahid Kaveh 14, Shahid Kaveh Blvd., Mashhad, Khorasan Razavi, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3871 3801

Email

ak.pr@mums.ac.ir

Web page address

https://akbar.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Central Organization of Mashhad University of Medical Sciences, Knowledge and Health Town, between Al-Shahidi Square and Shahid Javan Square, end of Shahid Fakuri Boulevard, Mashhad, Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3882 8883

Fax

Email

MDS.Dean@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Parisan Omidvar

Position

Pediatric Specialist Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Akbar Children's Superspecialty Hospital, opposite Kaveh 14, Mashhad, Razavi Khorasan

City

Mashhad

Province

Razavi Khorasan

Postal code

9177897157

Phone

+98 51 3871 3801

Email

pari.san68124@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Parisan Omidvar

Position

Pediatric Specialist Assistant

Latest degree

Medical doctor

Other areas of specialty/work

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+98 51 3871 3801

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pari.san68124@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Phone

+98 51 3871 3801

Email

pari.san68124@gmail.com

Web page address

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

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable