

# 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) or minimally 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

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+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

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+98 51 3882 8883

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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

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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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## Person responsible for updating data

#### 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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**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