Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Video Assisted thoracoscopic surgery(VATS) with Reteplase fibrinolytic injection in the pleural space through chest tube in children with empyema

Protocol summary

Study aim
Comparison of the effect of thoracoscopic decortication (VATS) with fibrinolytic injection into the pleural space through the chest tube in children with empyema

Design
This single blind 3 phase of clinical trial study is performed on 60 patients who are randomly assigned to two groups of treatment with ratplasma and thoracoscopic decortication surgery.

Settings and conduct
This study was performed in 1400 in Imam Hossein (AS) Hospital in Isfahan. This study is a single blind and the person examining the outcome of treatment is unaware of the treatment of patients.

Participants/Inclusion and exclusion criteria
In this study, patients under 15 years of age with empyema stage 2 who are admitted to Imam Hossein Hospital in Isfahan for treatment are studied. The incidence of drug allergies and changes in treatment methods are considered as exclusion criteria.

Intervention groups
In this clinical trial study, 60 patients with empyema diagnosis were divided into two groups of 30. In the fist group undergon video assisted thoracoscopic surgery and in the second group 0.1 mg/kg Reteplase was Injected into the pleural space through chest tube.

Main outcome variables
Duration of hospital stay, Duration of hospitalization in intensive care unit, Duration of receiving antibiotics, Duration of fever, Duration of dyspnea, Duration of chest tube

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N51**
Registration date: **2021-02-02, 1399/11/14**
Registration timing: **prospective**

Last update: **2021-02-02, 1399/11/14**
Update count: **0**

Registration date
2021-02-02, 1399/11/14

Registrant information

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Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-08, 1400/01/19

Expected recruitment end date
2022-03-19, 1400/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Video Assisted thoracoscopic surgery(VATS) with Reteplase fibrinolytic injection in the

pleural space through chest tube in children with empyema

Public title
Comparison of the effect of retplasia and surgery in the treatment of infection around the pleura
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
known stage 2 empyema candidate for VATS surgery or fibrinolytic injection age range 15-1 years parental consent to participate in the study
Exclusion criteria:
previous lung and chest surgery Having a coagulation disorder prohibition of the use of fibrinolytic drugs
Age
From **1 year** old to **15 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of patients is done using "Random Allocation Software: RAS". In the mentioned software, the total number of sample sizes along with the number of groups of subjects are entered into the software. The software output includes a list that randomly distributes all patients in two groups. According to the time of referral, patients are distributed in two groups according to the mentioned list so that the sample size reaches the required number in each group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The method of blinding is that the patients are treated by the researcher according to the randomization list, but the outcome of the treatment is checked by a pediatric surgeon who is unaware of the type of treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Ethic committee, Research faculty, Isfahan University of Medical Sciences, Hezarjerib street
City
isfahan
Province
Isfehan
Postal code
8434193474
Approval date
2020-01-20, 1398/10/30
Ethics committee reference number
IR.MUI.MEd.REC.1398.576

Health conditions studied

1

Description of health condition studied
empyema
ICD-10 code
J86.9
ICD-10 code description
Pyothorax without fistula

Primary outcomes

1

Description
Changes in severity of Empyema
Timepoint
Two weeks after treatment
Method of measurement
clinical evaluation

2

Description
Length of hospitalization
Timepoint
End of the treatment
Method of measurement
Patient record

3

Description
Duration of hospitalization in the intensive care unit
Timepoint
Time to leave the intensive care unit
Method of measurement
Patient record

4

Description
Duration of receiving antibiotics
Timepoint
End of treatment

Method of measurement
Patient record

5

Description
Duration of the chest tube
Timepoint
End of treatment
Method of measurement
Patient record

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, patients undergo thoracoscopic decoction surgery.
Category
Treatment - Surgery

2

Description
Intervention group 2: In this group, the fibrinolytic drug Retplase made by Osweh Pharmaceutical Company under the brand name Retelies containing 18 mg of Retplase at a dose of 0.1 mg / kg is injected through the chest tube into the pleural space with empyema.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam hosein hospital
Full name of responsible person
Hamidreza Kaviani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Hamidreza Kaviani
Position
Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The plan belongs to a government agency and cannot be shared.
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