

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

simple tube thoracostomy versus surgical debridement in complicated parapneumonic empyema management

Protocol summary

Study aim

Comparison the success rate of two different treatment procedures (simple drainage with chest tube and surgical debridement) in dealing with patients with empyema following complicated pneumonia

Design

This study is a randomized clinical trial. The statistical population consists of 104 patients with second phase empyema who are admitted to the hospital. The patients are alternately divided into two groups, each of 52, in the order of hospitalization.

Settings and conduct

This study is carried out in Surgery Department of Imam Khomeini Hospital in Tabriz and Shariati Hospital in Isfahan. After hospitalization, the patients are divided into two groups; one group is treated with simple thoracostomy and the other group with surgical debridement.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with parapneumonic empyema; patients should be in the second phase of the empyema; Exclusion criteria: impossibility of anesthesia due to the associated conditions that increases the risk of surgical treatment; the presence of bronchopleural fistula; empyema with multiple loculations that is not treated only using the chest tube; empyema in the first or fifth phase; empyema after surgery or trauma.

Intervention groups

one group has undergone open or thoracoscopic surgical procedure for draining empyema and debridement of the loculations and the other group is treated with simple tube thoracostomy

Main outcome variables

Complications (fever, respiratory distress and difficulty in breathing), duration of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170504033818N2**
Registration date: **2018-07-27, 1397/05/05**
Registration timing: **retrospective**

Last update: **2018-07-27, 1397/05/05**

Update count: **0**

Registration date

2018-07-27, 1397/05/05

Registrant information

Name

Behnam Yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4229 1111

Email address

dr.yazdani@pmd.iaun.ac.ir

Recruitment status

Recruitment complete

Funding source

treatment is covered by social insurance and patients will be treated free in hospital and research costs are provided by the researcher.

Expected recruitment start date

2003-08-23, 1382/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

2003-08-23, 1382/06/01

Actual recruitment end date

2015-08-23, 1394/06/01

Trial completion date

empty

Scientific title

simple tube thoracostomy versus surgical debridement in complicated parapneumonic empyema management

Public title

simple tube thoracostomy versus surgery in pleural infection management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

suffering from empyema - that has been proved using pleural fluid aspiration - due to the fluid accumulation following pneumonia undergoing the second phase of the empyema

Exclusion criteria:

impossibility of anesthesia due to the associated conditions that increases the risk of surgical treatment the presence of bronchopleural fistula empyema with multiple loculations that is not treated only using the chest tube. empyema in the first or third phase empyema after surgery or trauma

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Actual sample size reached: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are alternately divided into two groups in the order of hospitalization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2017-01-09, 1395/10/20

Ethics committee reference number

ir.tbzmed.rbc.1395.1278

Health conditions studied

1

Description of health condition studied

empyema

ICD-10 code

J86

ICD-10 code description

Pyothorax

2

Description of health condition studied

empyema after pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified

3

Description of health condition studied

pleural effusion

ICD-10 code

J90

ICD-10 code description

Pleural effusion, not elsewhere classified

4

Description of health condition studied

empyema without fistula

ICD-10 code

J86.9

ICD-10 code description

Pyothorax without fistula

Primary outcomes

1

Description

complications after discharge

Timepoint

one week and one month

Method of measurement

Fever, respiratory distress and difficulty in breathing

2

Description

duration of each treatment procedure

Timepoint

from the beginning of the patient's admission to the end of the medication taking

Method of measurement

the number of the recorded days

Secondary outcomes

1

Description

Recurrence after recovery

Timepoint

one week and one month after discharge

Method of measurement

signs , symptoms and paraclinical results

2

Description

The duration of hospitalization

Timepoint

The date of admission to patient discharge

Method of measurement

the number of the recorded days

3

Description

the duration of having chest tube

Timepoint

From the chest tube insertion to its removal

Method of measurement

the number of the recorded days

4

Description

duration of each treatment procedure

Timepoint

from the beginning of the patient's admission to the end of the medication taking

Method of measurement

the number of the recorded days

Intervention groups

1

Description

The intervention group are treated by a simple Tube Thoracostomy .

Category

Treatment - Surgery

2

Description

The control group are prepared for surgery and undergo debridement for draining empyema and inserting the chest tube.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Behnam Yazdani

Street address

Shariati Street

City

Isfahan

Province

Isfahan

Postal code

8173745384

Phone

+98 31 3627 2001

Email

yazdanibehnam@yahoo.com

2

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Behnam Yazdani

Street address

Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166615573

Phone

+98 41 3337 3907

Email

yazdanibehnam@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Najafabad Branch

Full name of responsible person

Behnam Yazdani

Street address

Shariati hospital

City

Isfahan

Province

Isfahan

Postal code

8173745384

Phone

+98 31 3627 2001

Email

yazdanibehnam@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University Najafabad Branch

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

Islamic Azad University Najafabad Branch

Full name of responsible person

Shima jafari jebeli

Position

medical intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Shariati Hospital

City

Isfahan

Province

Isfahan

Postal code

8173745384

Phone

+98 31 3627 2001

Fax

Email

shimajafari8998@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University Najafabad Branch

Full name of responsible person

Behnam Yazdani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

thorax surgery

Street address

Dr shariati Hospital

City

Isfahan

Province

Isfahan

Postal code

8173745384

Phone

+98 31 3628 1630

Fax

Email

dr.yazdani@pmd.iaun.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University Najafabad Branch

Full name of responsible person

Behnam Yazdani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Shariati hospital

City

Isfahan

Province

Isfahan

Postal code

8173745384

Phone

+98 31 3628 1630

Fax

Email

dr.yazdani@pmd.iaun.ac.ir

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

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