

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of autolog fibrin glue use on the improvment of air leak after thoracic surgery

Protocol summary

Study aim

This study aimed to compare pulmonary air leak after surgery between patients that use fibrin glue at the end of surgery and those with routine method.

Design

Randomized, parallel groups, single blinded, phase 3 on 40 patients. The random permuted block design is used for randomization and for the concealment of permutations in order to reduce the predictability of randomization, the closed envelopes will be used..

Settings and conduct

The study will be done in Thoracic Surgery Department of Ghaem Hospital in Mashhad University of Medical Sciences. In the intervention group, 50 cc's of blood will be taken from the patients two days before the surgery and about 5 cc's of autologous fibrin glue will be processed and sprayed on the damaged surfaces of the lung parenchyma in the final stage of the surgery . In the control group, surgery is performed routinely. Furthermore, the data analyst will also be unaware of the allocation of patients to groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients who are candidate for thoracic surgery
Exclusion criteria: Patients with sever comorbidity such as renal failure , cardio-pulmonary failure and liver failure

Intervention groups

In intervention group , the fibrin glue which is processed from the patient's own plasma is sprayed on the surface of lung parenchyma at the end of pulmonary surgery .In the control group, surgery is performed as usual.

Main outcome variables

The amount and duration of air leak from the test tubes
Chest tube drain Pulmonary complications after surgery
The length of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190408043196N1**
Registration date: **2020-07-12, 1399/04/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-12, 1399/04/22**

Update count: **0**

Registration date

2020-07-12, 1399/04/22

Registrant information

Name

reza rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2840

Email address

rezaeir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of autolog fibrin glue use on the improvment of air leak after thoracic surgery

Public title

Effect of fibrin glue use on the improvement of air leak

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are candidate for thoracic surgery will be included.

Exclusion criteria:

Patients who have a sever comorbidity such as renal failure , cardio-pulmonary failure and liver failure will be excluded from the study.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking as a method of restricted randomization that ensures the treatment groups are balanced at the end of every block will be used in this study. Using Random Allocation Software, random permuted blocks of different sizes 4 or 6, each block containing an equal number of subjects from each group, are designed and a unique identification code is assigned to each block. In this manner, after completion of a block, an equal number of subjects will be enrolled in each group. While referring to the doctor, one of the envelopes is randomly selected and according to the order of its contents, each patient is assigned to one of the groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst will not know which group is A or B.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of mashhad University of Medical Sciences

Street address

Thoracic surgery Department, Ghaem hospital, Ahmadabad street.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.MUMS.REC.1397.324

Health conditions studied**1****Description of health condition studied**

Turactomy and pulmonary resections or lung decoration (For empyema treatment)

ICD-10 code

J86

ICD-10 code description

Pyothorax

Primary outcomes**1****Description**

Duration of air leak

Timepoint

After surgery on a daily basis during the hospital stay

Method of measurement

Duration of air leakage after surgery will be recorded during hospitalization.

Secondary outcomes**1****Description**

length of hospital stay

Timepoint

After surgery on a daily basis during the hospital stay

Method of measurement

Counting the days of hospitalization of the patient from the day of surgery to discharge from the hospital

2**Description**

Drainage of chest tube

Timepoint

After surgery on a daily basis during the hospital stay

Method of measurement

The drainage of chest tube after surgery is examined in the daily visit of patients during hospitalization.

3**Description**

Postoperative pulmonary complications

Timepoint

during hospitalization and 7 and 30 days after surgery

Method of measurement

Postoperative pulmonary complications will be examined by a specialist during hospitalization and 7 and 30 days after surgery.

Intervention groups

1

Description

In the intervention group, 50 cc's of blood will be taken from the patients two days before the surgery and about 5 cc's of autologous fibrin glue will be processed and sprayed on the damaged surfaces of the lung parenchyma in the final stage of the surgery.

Category

Treatment - Other

2

Description

Control group: Surgery is performed routinely.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Reza Rezaei

Street address

Thoracic surgery unit, Qhaem hospital, Ahmadabad street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3801 2840

Email

rezaeir@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

Ghoreishi department , Daneshgah street , Mashhad ,

Khorasan Razavi

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Fax

+98 51 3843 0249

Email

tafaghodim@mums.ac.ir

Web page address

<https://v-research.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

Reza Rezaei

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Thoracic surgery unit, Ghaem hospital, Ahmadabad street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3801 2840

Email

rezaeir@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reza Rezaei

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Thoracic surgery unit, Qhaem hospital, Ahmadabad street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3801 2840

Email

rezaeir@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Reza Rezaei

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Thoracic surgery unit, Ghaem hospital, Ahmadabad street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 915 306 7052

Email

rezaeir@mums.ac.ir

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

There is no further information

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

Not applicable

Data Dictionary

Not applicable