

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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

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**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

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Thoracic surgery unit, Ghaem hospital, Ahmadabad street

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## 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**

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## 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

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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**

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