Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of postoperative outcomes in lung hydatid cyst surgery in two methods with and without captonage

Protocol summary

Study aim
Prevent air leakage from the surgical site
Design
This study will be a double-blind, parallel clinical trial comparing two groups on 64 patients with pulmonary hydatid cysts at Al-Zahra Medical Center. Patients will be completely randomly divided into two groups using Excel software.
Settings and conduct
This study will be a double-blind, parallel clinical trial comparing two groups on 64 patients with pulmonary hydatid cysts at Al-Zahra Medical Center. Patients will be completely randomly divided into two groups using Excel software.
Participants/Inclusion and exclusion criteria
Inclusion criteria: All candidates for surgery with pulmonary hydatid cyst Age between 18 and 75 years Consent to participate in the study Exclusion criteria: Concurrent pulmonary comorbidity such as asthma and COPD
Intervention groups
Individuals in the intervention group, after performing the standard surgical procedure, undergo capitonnage (after draining the cyst, the remaining cyst wall is sutured and collected), while the control group ends without capitonnage.
Main outcome variables
Air Leak

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221108056446N16**
Registration date: **2025-05-14, 1404/02/24**
Registration timing: **registered_while_recruiting**
Last update: **2025-05-14, 1404/02/24**
Update count: **0**
Registration date
2025-05-14, 1404/02/24

Registrant information
Name
Mehdi Mahmoodkhani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 913 686 3733
Email address
mahmoodkhani@med.mui.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-05-21, 1403/03/01
Expected recruitment end date
2025-05-22, 1404/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of postoperative outcomes in lung hydatid cyst surgery in two methods with and without captonage

Public title
outcomes in lung hydatid cyst surgery in two methods with and without captonage
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

All candidates for surgery with pulmonary hydatid cysts Age between 18 and 75 years Consent to participate in the study

Exclusion criteria:

Concurrent pulmonary comorbidities such as asthma and COPD

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

With the convenience sampling method, the referring individuals who are eligible for the study are randomly divided into two groups: case and control. In this study, the division of individuals is done using the four-way permutation block method. In this method, A represents the individual who receives the intervention and B represents the individual who is in the control group. Considering the four-way block, we give the AABB permutation code 0, the ABAB permutation code 1, ABBA code 2, BAAB code 3, BBAA code 4, and BABA codes 5 to 9. Then, using the random number table, we randomly select a starting point and then consider the numbers in rows or columns. Considering the order of the numbers in the table, we assign the corresponding permutation to each number we encounter. Finally, 64 people will be divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a randomized, double-blind clinical trial that will be conducted at Al-Zahra Medical Center, Isfahan University of Medical Sciences. In this study, patients and the statistical analyst will remain blind. In this way, the patient does not know about the suturing of the cyst wall, and the statistical analyst does not know which group of patients each set of data belongs to. Patients will be divided into two groups using the four-way permutation block method in the rand function of Excel software.

Placebo

Not 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, Isfahan University of Medical Sciences

Street address

Hazar Jarib Street, Azadi Square

City

Esfahan

Province

Isfehan

Postal code

8174673461

Approval date

2025-05-05, 1404/02/15

Ethics committee reference number

IR.MUI.MED.REC.1404.061

Health conditions studied

1

Description of health condition studied

lung hydatid cyst

ICD-10 code

O01.0

ICD-10 code description

Classical hydatidiform mole

Primary outcomes

1

Description

Air Leak

Timepoint

Three months after surgery

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the standard surgical procedure, patients undergo capitonnage (after the cyst is drained, the remaining cyst wall is sutured and collected).

Category

Treatment - Surgery

2

Description

Control group: Patients do not undergo capitonnage after the standard surgical procedure, so the cyst wall is not sutured.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-zahra Hospital

Full name of responsible person
Hamid Talebzadeh

Street address
Al-zahra Hospital

City
Esfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 913 314 0640

Email
talebzadeh.h@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Gholamreza Asgari

Street address
Al-zahra Hospital, Sofeh

City
Esfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3668 0048

Email
mui@mui.ac.ir

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

10

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
Hamid Talebzadeh

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

Street address
Al-Zahra Hospital, Soffe Street

City
Esfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 913 314 0640

Email
talebzadeh.h@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Hamid Talebzadeh

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
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Street address
Al-Zahra Hospital, Soffe Street

City
Esfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 913 314 0640

Email
talebzadeh.h@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Pourya Akbari Nasab
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Al-Zahra Hospital, Soffe Street
City
Esfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 913 314 0640
Email
talebzadeh.h@med.mui.ac.ir

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