

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 capitonage (after draining the cyst, the remaining cyst wall is sutured and collected), while the control group ends without capitonage.

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

Isfahan

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

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8174675731

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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

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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

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

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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

Specialist

Other areas of specialty/work

General Surgery

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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

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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