

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Povidone Iodine 10% and hypertonic saline 5% on their scolical effect during surgery and evaluation of recurrence and complications after pulmonary hydatid cyst surgery

Protocol summary

Study aim

Comparison of Povidone Iodine 10% and hypertonic saline 5% on their scolical effect during surgery and evaluation of recurrence and complications after pulmonary hydatid cyst surgery

Design

Two arm parallel group randomized clinical trial with 60 patients in two groups. Randomization method is the table of random numbers.

Settings and conduct

The study is conducted in Emam Khomeini hospital & Sina hospital in Tehran. This is single blinded trial and the patients have no information about scolical agents used in their surgeries.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who suffer from pulmonary hydatid cyst Exclusion criteria: Patients with ruptured or infected pulmonary hydatid cyst, or concomitant non-pulmonary hydatid cyst or history of hydatid cyst surgery in any organs

Intervention groups

Patients are randomly divided into two groups, in one group betadine 10% and in the other one hypertonic saline 5% are used as scolical agents during surgery. Patients must meet the inclusion and exclusion criteria.

Main outcome variables

Patients are followed for 1 year: complications of treatment such as post op air leak; empyema; and recurrence of cysts are also compared between the two groups based on the chest radiograph. Besides, the scolical effect of agents is compared by evaluation of samples sent during the operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220616055193N1**

Registration date: **2022-06-21, 1401/03/31**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-21, 1401/03/31**

Update count: **0**

Registration date

2022-06-21, 1401/03/31

Registrant information

Name

Matin Vahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

mvahedi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-20, 1401/03/30

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Povidone Iodine 10% and hypertonic saline 5% on their scolical effect during surgery and

evaluation of recurrence and complications after pulmonary hydatid cyst surgery

Public title

Comparison of Betadine 10% and saline 5% on recurrence and complications of pulmonary hydatid cyst surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who suffer from pulmonary hydatid cyst

Exclusion criteria:

Ruptured or infected pulmonary hydatid cyst
Concomitant non-pulmonary hydatid cyst
History of hydatid cyst surgery in any organs

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation sequence and list of blocks will be obtained by the software consultant with statistics. The <https://www.sealedenvelope.com> website is a useful site for generating random sequences for block type randomization. This site is designed so that there is no limit to the number of random allocation groups. The block method is used to generate random allocation sequences. Patients will be selected according to the criteria of the researcher by sequential sampling method and will be randomly divided into two groups intervention and control. Randomization will be done in secret; after obtaining informed consent, which group (each intervention group) will be randomly assigned to each patient according to the specified blocks, as the participatory education for the patient and caregiver will take place, each patient's caregiver code will also be included. The random assignment sequence is obtained by the software's statistical and statistical expert. Patients and caregivers who have the inclusion criteria are enrolled by the researcher. Participants will be assigned randomly via specified blocking to hide the random assignment of the group names in the random assignment sequence. Participants were coded in order of entry into the study and assigned to the two intervention group.

Blinding (investigator's opinion)

Single blinded

Blinding description

None of the patients and analysts are aware of the scolicidal agent used during surgery. The surgeons who

is also responsible for postoperative follow up are aware of the type of agent used for each patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Imam Khomeini Hospital Complex - Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Tohid Squire

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-01-11, 1400/10/21

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.406

Health conditions studied

1

Description of health condition studied

Hydatid cyst

ICD-10 code

B67.9

ICD-10 code description

Echinococcosis, other and unspecified

Primary outcomes

1

Description

Post op air leakage

Timepoint

1, 3, 6, 12 months post op

Method of measurement

Chest radiograph

2

Description

Empyema formation

Timepoint

1, 3, 6, 12 months post op

Method of measurement

Chest radiograph

3**Description**

Hydatid cyst recurrence

Timepoint

1, 3, 6, 12 months post op

Method of measurement

Chest radiograph

4**Description**

viability of scolex in hydatid cyst fluid

Timepoint

Post op

Method of measurement

Microscope slide

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: During surgery, following aspiration of the cyst, installation of a Povidone Iodine 10% as scolicidal agent is done to kill the parasite, then evacuation of the parasitic material and preservation or partial resection of the pericyst will be done.

Category

Treatment - Drugs

2**Description**

Intervention group: During surgery, following aspiration of the cyst, installation of a Hypertonic saline 5% as scolicidal agent is done to kill the parasite, then evacuation of the parasitic material and preservation or partial resection of the pericyst will be done.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Khomeini hospital

Full name of responsible person

Matin Vahedi

Street address

Emam Khomeini Hospital Complex, Tohid square

City

Tehran

Province

Tehran

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2**Recruitment center****Name of recruitment center**

Sina hospital

Full name of responsible person

Matin Vahedi

Street address

Sina hospital, Emam Khomeini st.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotoohi

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Keshavarz blvd

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1417653761

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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

Tehran 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

Phone

+98 21 6634 8500

Email

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Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Matin Vahedi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Thoracic Surgery

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Matin Vahedi

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Latest degree

Subspecialist

Other areas of specialty/work

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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