

# 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

**Postal code**

1419733141

**Phone**

+98 21 6119 0000

**Email**

mvahedi@sina.tums.ac.ir

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

Sina hospital

**Full name of responsible person**

Matin Vahedi

**Street address**

Sina hospital, Emam Khomeini st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8500

**Email**

mvahedi@sina.tums.ac.ir

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

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Akbar Fotoohi

**Street address**

Keshavarz blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 8163 3686

**Email**

vcr@tums.ac.ir

**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**

mvahedi@sina.tums.ac.ir

**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

**Street address**

Sina hospital, Emam Khomeini st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8500

**Email**

mvahedi@sina.tums.ac.ir

**Person responsible for updating data****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**

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**Postal code**

1136746911

**Phone**

+98 21 6634 8500

**Email**

mvahedi@sina.tums.ac.ir

**Person responsible for scientific 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

**Street address**

Sina hospital, Emam Khomeini st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**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