Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Povidone Iodine 10% and hypertonic saline 5% on their scolicidal 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 scolicidal 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 scolicidal 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 scolicidal 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 scolicidal 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 scolicidal 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 Squre
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.
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1136746911
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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
Street address
Keshavarz blvd
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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

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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Sina hospital, Emam Khomeini st.
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Person responsible for scientific inquiries

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Person responsible for updating data

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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