Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of chlorhexidine gluconate 0.04% with hypertonic saline as a scolcidal agent during liver hydatid surgery and the recurrence of hydatid cyst

Protocol summary

Study aim

Comparison of the effect of 0.04% chlorhexidine gluconate with hypertonic saline as a scolexicide during liver hydatid surgery and the rate of hydatid cyst recurrence.

Design

This is a phase III randomized controlled clinical trial with parallel groups and double blinding. Patients are allocated using balanced block randomization (1:1) into two groups (total 40).

Settings and conduct

Patients with hepatic hydatid cyst referred to Shahrekord Kashani Hospital will be randomly assigned to two groups receiving either 0.04% chlorhexidine gluconate or hypertonic saline as intraoperative scolicidal agents, and 6-month recurrence of hydatid cyst will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Patients with hepatic hydatid cysts with indications for surgery 2. Consent to participate in the study 3. Age between 18-65 years 4. There should be no contraindications for surgery Exclusion criteria: 1. Patients with severe comorbidities 2. Patients with a history of sensitivity to chlorhexidine gluconate 3. Patients with recurrent hydatid cysts 4. Patients undergoing re-surgery for hydatid cysts 5. Lack of cooperation and unwillingness to enter the study 6. Use of albendazole before surgery

Intervention groups

All surgical procedures are the same in both groups, only the type of solution used differs. Hypertonic saline solution is used in one group and chlorhexidine solution is used in the other group.

Main outcome variables

Recurrence rates after surgery

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20250105064277N2**
Registration date: **2026-04-22, 1405/02/02**
Registration timing: **prospective**

Last update: **2026-04-22, 1405/02/02**
Update count: **0**

Registration date

2026-04-22, 1405/02/02

Registrant information

Name

Rasoul Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-30, 1405/02/10

Expected recruitment end date

2027-04-30, 1406/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of chlorhexidine gluconate 0.04% with hypertonic saline as a scolcidal agent during liver hydatid surgery and the recurrence of hydatid cyst

Public title
Comparison of two solutions used during hydatid cyst surgery to prevent disease recurrence

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with hepatic hydatid cysts with an indication for surgery Willingness to participate in the study and provision of informed consent Age between 18 and 65 years No contraindication to surgery

Exclusion criteria:
Patients with severe concomitant systemic diseases History of hypersensitivity to chlorhexidine gluconate Patients with recurrent hydatid cysts Patients undergoing reoperation for hydatid cyst Lack of cooperation or refusal to participate in the study Use of albendazole prior to surgery

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **40**
Each participant contributes one sample corresponding to one surgical treatment of hepatic hydatid cyst and receives one scolicidal intervention. No participant provides multiple samples.

Randomization (investigator's opinion)
Randomized

Randomization description
This randomized clinical trial employs balanced block randomization with an allocation ratio of 1:1 to assign eligible patients into two intervention groups. Block randomization is used to ensure balanced group sizes throughout the recruitment period. Variable block sizes (e.g., 4 and 6) are generated randomly to prevent predictability of treatment allocation. The exact block sizes are not disclosed to the research team to minimize selection bias.

Blinding (investigator's opinion)
Double blinded

Blinding description
A double-blind design is implemented in this study. Blinding is maintained as follows: 1. Participants: Patients are unaware of which scolicidal solution is used during surgery. Both solutions are presented in identical, unlabeled packages. 2. Surgeons and Clinical Staff: The operating surgeon and clinical team performing patient care are blinded to group allocation. Intervention packages are prepared by an independent supervisor and identified only by coded 1 and 2 labels. 3. Data Collectors and Outcome Assessors: Data collection, form completion, and outcome evaluation (including CT scan assessment for recurrence) are performed by investigators who remain blinded to treatment allocation. 4. Data Analysts: Statistical analyses are conducted using coded group labels (Group 1 and Group 2), without revealing the actual intervention identity. 5. Study Supervisor: Only the study supervisor has access to the allocation code and does not participate in patient recruitment, treatment, data collection, or data analysis. Thus, blinding is preserved from patient enrollment through intervention delivery, outcome assessment, and statistical analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Shahrekord University of Medical Sciences

Street address
University Headquarters, Kashani Boulevard

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Approval date
2025-09-17, 1404/06/26

Ethics committee reference number
IR.SKUMS.MED.REC.1404.106

Health conditions studied

1

Description of health condition studied
Hepatic hydatid cyst; Liver echinococcosis; Hydatid cyst surgery; Scolicidal agent; Chlorhexidine gluconate; Hypertonic saline; Hydatid cyst recurrence

ICD-10 code
B67.0

ICD-10 code description

Echinococcus granulosus infection of liver

Primary outcomes

1

Description
Proportion of patients with recurrent hepatic hydatid cyst detected by CT scan within 6 months after surgery
Timepoint
6-month postoperative follow-up
Method of measurement
Computed Tomography imaging of the liver for detection of hydatid cyst recurrence

Secondary outcomes

empty

Intervention groups

1

Description
Group 1: Hypertonic saline group Group 2: Chlorhexidine gluconate at a concentration of 0.04% as a scoliosis agent during liver hydatid cyst surgery; topical application within the surgical field and cystic cavity according to standard open surgical technique; once during surgery.
Category
Treatment - Surgery

2

Description
Intervention group: Hypertonic saline as a scolicidal agent during hepatic hydatid cyst surgery; topical application in the operative field and cyst cavity; single use during surgery.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital, Shahrekord
Full name of responsible person
Rasoul Rahimi
Street address
Parastar Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
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Central Administration,Kashani Boulevard
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Rasoul Rahimi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the single-center design, limited sample size, and to ensure confidentiality of patient information, there is no plan to share individual participant data outside the research team.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The full study protocol, informed consent form, final clinical study report, and data dictionary will be made available upon reasonable request to the corresponding investigator after completion of the study. Individual participant data will not be shared in order to protect patient confidentiality. The data dictionary includes definitions of study variables, data types, and coding structure.
When the data will become available and for how long
Study documents will be available upon reasonable request after publication of results.
To whom data/document is available
Researchers affiliated with academic and scientific institutions may request access to study documents upon reasonable request. Provision of documents will be subject to approval by the principal investigator and compliance with confidentiality principles. Individual participant data will not be shared.
Under which criteria data/document could be used
Access to study documents is permitted only for scientific and academic research purposes. Any commercial use or publication without proper citation is prohibited. Secondary analyses are limited to scientific descriptive and comparative analyses and must comply with confidentiality principles. Access is subject to submission of a written request, statement of intended use, and commitment to confidentiality. Provision of documents requires approval of the principal investigator. Individual participant data will not be shared under any circumstances.
From where data/document is obtainable
rahimi.r@skums.ac.ir
What processes are involved for a request to access data/document
Requests will be reviewed by the principal investigator, and the requested documents will be provided as soon as possible after approval of the request.
Comments