

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of chlorhexidine gluconate 0.04% with hypertonic saline as a scolical 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 scolical 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)

Phone

+98 38 3333 0061

Email address

rahimi.r@skums.ac.ir

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 scolical 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 scolical 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 scolical 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; Scolical agent; Chlorhexidine gluconate; Hypertonic saline; Hydatid cyst recurrence

ICD-10 code

B67.0

ICD-10 code description

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 scolical 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

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816758915

Phone

+98 38 3226 4841

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Ali Hassanpour Dehkordi

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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