

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of the results of Simple and Modified PAIR methods in the treatment of liver hydatid cyst

Protocol summary

Study aim

Comparative study of the results of Simple and Modified PAIR methods in the treatment of liver hydatid cyst

Design

This is a non-blinded randomized clinical trial with a parallel design. This randomized study will be conducted on 24 patients with hepatic hydatid cysts. A simple randomization method will be used for randomization, and participants will be assigned to two intervention groups.

Settings and conduct

This study, which will be conducted at Imam Reza Hospital in Kermanshah, is not blinded. Before the intervention begins, the size and volume of the cyst, as well as the presence of a fluid component in the cavity, irregularity, and thickening of the cyst wall, will be carefully examined and recorded in a checklist for each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Individuals diagnosed with hepatic hydatid cysts. Exclusion criteria: Patients concurrently infected with pulmonary hydatid cysts;

Intervention groups

In the Simple PAIR method, an 18-gauge Shiba needle is inserted into the cyst under ultrasound guidance, and a portion of the cyst contents is evacuated with volume control and then aspirated. The entire cyst contents are aspirated and the cyst is filled with a mixture of nonionic contrast medium and saline solution ($\frac{1}{2}$ contrast medium + $\frac{1}{2}$ saline solution 0.09% [NaCl]) equal to the aspirated amount. The contents of the cyst cavity are aspirated again after the cystogram, and then absolute alcohol (97% ethyl alcohol from Merck) is injected in a volume equivalent to 30% of the aspirate. In the Modified PAIR method, the cyst is punctured with an 18-gauge Shiba needle and a hydrophilic wire is inserted into it. Then, the dissecting route is inserted and fixed inside the cyst with a thin 6f dilator and the thinnest available 8f

catheter using the Seldinger method.

Main outcome variables

Hydatid cyst volume; Hydatid cyst size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N267**

Registration date: **2025-09-30, 1404/07/08**

Registration timing: **prospective**

Last update: **2025-09-30, 1404/07/08**

Update count: **0**

Registration date

2025-09-30, 1404/07/08

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-10-12, 1404/07/20

Expected recruitment end date

2026-11-11, 1405/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the results of Simple and Modified PAIR methods in the treatment of liver hydatid cyst

Public title

Comparative study of two treatment of liver hydatid cyst

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent People diagnosed with hepatic hydatid cysts

Exclusion criteria:

Patients who are simultaneously infected with pulmonary hydatid cysts

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 24

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random method. 24 cards are selected and numbers from 1-24 are inserted on the cards. The cards are placed in an envelope. Two of the design partners take one card out of the envelope each time and announce the card number. Paired numbers are assigned to the intervention group and odd numbers to the control group

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kermanshah University of Medical Sciences, Ethics Committee of the Faculty of Medicine

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2025-04-27, 1404/02/07

Ethics committee reference number

IR.KUMS.MED.REC.1404.043

Health conditions studied**1****Description of health condition studied**

Liver Hydatid Cysts

ICD-10 code

B67.0

ICD-10 code description

Echinococcus granulosus infection of liver

Primary outcomes**1****Description**

Hydatid cyst size

Timepoint

First month, third and sixth months, and first year

Method of measurement

Using ultrasound

2**Description**

Hydatid cyst volume

Timepoint

First month, third and sixth months, and first year

Method of measurement

Using ultrasound

Secondary outcomes

empty

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

In the first intervention group (Simple PAIR method), an 18-gauge Shiba needle is inserted into the cyst under ultrasound guidance, and a portion of the cyst contents is evacuated with volume control and then aspirated. The entire cyst contents are aspirated and the cyst is filled with a mixture of nonionic contrast agent and saline solution ($\frac{1}{2}$ contrast agent + $\frac{1}{2}$ saline solution 0.09% [NaCl]) equal to the aspirated volume. The cyst cavity

contents are aspirated again after the cystogram, and then absolute alcohol (97% ethyl alcohol Merck) is injected in a volume equal to 30% of the aspirated volume.

Category

Treatment - Other

2**Description**

In the second intervention group (Modified PAIR method), the cyst is punctured with an 18-gauge Shiba needle and a hydrophilic wire is inserted into it. Then, the dissected route is inserted and fixed inside the cyst using a thin 6f dilator and the thinnest available 8f catheter using the Seldinger method.

Category

Treatment - Other

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

Emam Reza Hospital

Full name of responsible person

Dr. Mohammad Gharib Salehi

Street address

Emam Reza Hospital, Parastar Boulevard

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Zohreh Rahimi

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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

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Leila Arghand

Position

Radiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Gharib Salehi

Position

University faculty member

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity
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Latest degree
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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available