Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 (½ contrast medium + ½ 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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Recruitment status
Recruitment complete

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 (½ contrast agent + ½ 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

City

Kermanshah

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6715847141

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Email

Kumssalehi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Zohreh Rahimi

Street address

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

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Zrahimi@kums.ac.ir

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

Other areas of specialty/work

Radiology

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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

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Dr Mohammad Gharib Salehi

Position
University faculty member

Latest degree
Specialist

Other areas of specialty/work
Radiology

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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