Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Clinical Outcomes of open and laparoscopic surgery among pediatric patients with hydatid cysts: A randomized clinical trial

Protocol summary

Study aim

To compare the clinical and therapeutic outcomes of open surgery versus laparoscopic methods in pediatric patients undergoing surgery for hydatid cysts.

Design

This parallel randomized clinical trial, phase 3, single-blind , will be conducted among pediatric patients with hydatid cysts presenting to Tabriz Children's Hospital who have an indication for either open or laparoscopic surgery. Patient allocation will be performed using balanced block randomization using the rand function in STATA.

Settings and conduct

This clinical trial will be conducted on patients (children) with hydatid cysts referred to the Children's Educational, Research, and Treatment Center of Tabriz. The target population will be children aged 2 to 18 years with hepatic hydatid cysts. One group will be treated with open surgery, and the other will undergo laparoscopic surgery. The surgeon and pediatrician will be the same for both groups. Given the open and surgical nature of the interventions, blinding the surgeon is not possible. Therefore, a single-blind process will be implemented, solely for the analyzer and outcome assessor.

Participants/Inclusion and exclusion criteria

Children aged 2–18 years who have an indication for surgical treatment by either the laparoscopic or open approach ؛ ruptured cysts, particularly pulmonary cysts, cysts located in close proximity to major blood vessels, any contraindication to laparoscopic surgery, or an underlying or suspected malignancy.

Intervention groups

Laparoscopic surgery group: Patients assigned to this group will undergo laparoscopic surgical treatment for hepatic hydatid cysts. Open surgery group: Patients assigned to this group will undergo conventional open surgical treatment for hepatic hydatid cysts.

Main outcome variables

Comparison of operative time between the two groups

Comparison of length of hospital stay between the two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260513069381N1**
Registration date: **2026-10-09, 1405/07/17**
Registration timing: **prospective**

Last update: **2026-10-09, 1405/07/17**
Update count: **0**

Registration date

2026-10-09, 1405/07/17

Registrant information

Name

Hosein Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3554 1221

Email address

aziziepid@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-02-14, 1405/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Clinical Outcomes of open and laparoscopic surgery among pediatric patients with hydatid cysts: A randomized clinical trial

Public title
Comparison of Clinical Outcomes of open and laparoscopic surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range between 2 - 18 years Clinical indication for open or laparoscopic surgery

Exclusion criteria:
Ruptured cysts Cysts near the vessels Contraindications to laparoscopy Patients with a history of malignancy

Age
From **2 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
The unit of randomization in this study will be the individual patient. Eligible patients will be randomly allocated to two groups using balanced permuted block randomization: the intervention group (laparoscopic surgery) and the control group (open surgery). The random allocation sequence will be generated using Stata version 14 by an independent epidemiologist who will not be involved in patient recruitment, delivery of the interventions, or outcome assessment. Fixed block sizes of four will be used, with two patients allocated to each treatment group within each block. The order of assignments within each block will be determined randomly. A total of five blocks will be generated to randomize the planned sample of 20 patients. To ensure allocation concealment, the randomization sequence generated by the independent epidemiologist will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). The envelopes will be opened sequentially, in numerical order, only after a patient has been confirmed to meet the eligibility criteria and has been enrolled in the study. This procedure will prevent the upcoming treatment allocation from being revealed or predicted before the patient's assignment. The epidemiologist responsible for generating the randomization sequence will have no involvement in patient recruitment or the surgical procedures.

Blinding (investigator's opinion)
Single blinded

Blinding description
The outcome assessor will not be present in the operating room during the surgical procedures. Following each surgery, the outcomes of interest will be assessed by extracting the relevant information from the patient's medical records and operative documentation. The outcome assessor will be blinded to the type of surgical procedure performed and will therefore be unaware of whether the patient underwent laparoscopic or open surgery. The statistical analyst will also remain blinded to treatment allocation throughout the data analysis process. In the statistical datasets and analysis software, the two study groups will be coded as Group A and Group B. The identity of the treatment groups will remain concealed from the statistical analyst until completion of the primary statistical analyses.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2026-09-16, 1405/06/25

Ethics committee reference number
IR.TBZMED.REC.1405.410

Health conditions studied

1

Description of health condition studied
Hydatid cysts

ICD-10 code
B67.0

ICD-10 code description
Echinococcus granulosus infection of liver

Primary outcomes

1

Description
The primary outcome of the study will be the comparison of surgical time/duration between groups.
Timepoint
Length of hospital stay
Method of measurement
Medical recorda and clinical observations in the surgery

Secondary outcomes

1

Description
Secondary outcomes will include surgical complications such as infection, recurrence, ulceration, pain intensity, and other clinical and paraclinical manifestations between the two methods.
Timepoint
At postoperative days 0 and 3, and at one week and one month following surgery.
Method of measurement
Infection, recurrence, and ulceration will be assessed based on clinical observation by the surgeon, and pain intensity will be measured using the Visual Analog Scale (VAS)

Intervention groups

1

Description
Intervention group: In this group, minimally invasive laparoscopic surgery will be performed in children with hepatic hydatid cysts by a single surgeon.
Category
Treatment - Surgery

2

Description
Control group: In the control group, open surgery will be performed in patients with the same condition and identical surgical indications.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Mardani Azar Hospital, Tabriz University of Medical Sciences, Tabriz, Iran
Full name of responsible person
Dr Ebrahim Farhadi
Street address
Road Traffic Injury Research Center (RTIR), Sadeghi St.,El Goli Ave.. P.
City
Tabriz
Province
East Azarbaijan
Postal code
5169780026
Phone
+98 41 3159 5005
Fax
+98 41 3159 5050
Email
mardaniazar@tbzmed.ac.ir
Web page address
https://mardaniazari.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Khosro Adibkia
Street address
Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 5921
Email
danesh@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Ebrahim Farhadi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric Surgery
Street address
Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 5921
Email
ibrahim.farhadi96@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ebrahim Farhadi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric Surgery
Street address
Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 5921
Email
ibrahim.farhadi96@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ebrahim Farhadi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric Surgery
Street address
Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 5921
Email
ibrahim.farhadi96@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is 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
Individual participant data will be made available after removing all direct and indirect identifiers, upon reasonable request and subject to ethical and confidentiality considerations. The data will be provided only to qualified researchers for valid scientific and research purposes and following review and approval of the request. The shared dataset will not contain names, national identification numbers, hospital record numbers, telephone numbers, addresses, or any other information that could directly or indirectly identify the participants.
When the data will become available and for how long
Access to the de-identified study documents and data files will begin 6 months after publication of the primary results of the study and will remain available for 5 years from the date access begins.
To whom data/document is available
The study data and supporting documents will be available upon request to qualified researchers affiliated with universities, research institutions, or other recognized academic and scientific organizations. Requests must be submitted for valid scientific research purposes and will be reviewed and approved before access to the de-identified data is granted.
Under which criteria data/document could be used
Access to the data and supporting documents will be granted only for valid scientific research purposes. Applicants must specify the research objective, research question, and general analytical approach in their request. Only de-identified data will be provided, and recipients must maintain data confidentiality and security and must not share the data with third parties.

Any attempt to re-identify participants will be strictly prohibited. The data must be used in accordance with applicable ethical and research regulations and only for the purposes approved in the request. Requests will be reviewed and approved by the study investigators before access is granted. Any publication resulting from the use of the shared data must appropriately acknowledge and cite the original study. Any proposed use beyond the scope of the original request will require a new request and additional approval.

From where data/document is obtainable

Applicants may submit requests for access to the de-identified study data and supporting documents directly to the principal investigator via the investigator's official institutional email address. The request should include the applicant's name and institutional affiliation, the purpose of the proposed research, the research question or objectives, and the general analytical approach. Requests will be reviewed by the study investigators and, if the specified eligibility criteria are met, will be processed through the same communication channel, with the requested data provided through a secure data-transfer mechanism. Contact information for the principal investigator: [Ebrahim Farhadi], Department of Pediatric Surgery, Tabriz University of Medical Sciences, Tabriz, Iran; Email: [ibrahim.farhadi96@gmail.com].

What processes are involved for a request to access data/document

Applicants must submit their request via the official email address of the principal investigator. The request must include the applicant's contact information, institutional affiliation, research purpose and question, general analytical approach, and intended use of the requested data. Each complete request will be reviewed within 14 business days to assess the completeness of the information and compliance with the data-access requirements. If additional information or documentation is required, the applicant will be contacted and asked to provide the necessary materials. Once the request is approved, the de-identified data and approved supporting documents will be provided to the applicant through a secure data-transfer mechanism within 30 business days of final approval. If a request is denied, the applicant will be informed of the decision and the reason for denial by email. The entire process, from receipt of a complete request to provision of the requested data, is expected to take no more than 44 business days.

Comments

No additional information is required at this time. Any data sharing will be conducted in accordance with applicable ethical requirements, participant confidentiality protections, and the data-access procedures and conditions described above.