

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Biliary Leakage between Laparoscopic Versus Open Surgery of Liver Hydatid Cyst: A Randomized Controlled Trial

Protocol summary

Study aim

To compare the frequency of post-operative outcomes vis. biliary leakage, post-operative pain, wound infection rate, recurrence of hydatid cyst disease and length of hospital stay between open versus laparoscopic surgery in patients with liver hydatid cyst disease.

Design

Randomized, controlled trial, parallel group design of 84 patient enrolled between June 2022 to January 2023 in a single center.

Settings and conduct

Surgical Unit-I, Nishtar Medical University/Hospital, Multan. Statistician was blinded in the study analysis i.e single blinded RCT.

Participants/Inclusion and exclusion criteria

Inclusion: 1. Gender; both male and female patients. 2. Age range; 18-60 years. 3. Patients with liver hydatid cyst with size ≥ 3 cm (as per operational definition)
Exclusion: 1. Severely anemic patients (Hb levels less than 8 g/dl) 2. Patients with recurrent disease, cysts in liver segment 1 and 7, concomitant cyst in other organs, cysto-biliary communication and patients with ruptured cyst (confirmed from patient record file and any suspected communication will be confirmed on CT). 3. Chronic liver disease (confirmed from patient record file). 4. Alcoholic abuse (patient's history, alcohol consumption for > 1 year) 5. Pregnant ladies

Intervention groups

Patients were categorized into group A for which hydatid disease surgery is by open method that is laparotomy and group B in which hydatid disease surgery is by laparoscopic surgery.

Main outcome variables

Biliary leakage, wound infection, or recurrence of hydatid cyst.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240503061640N3**

Registration date: **2024-09-28, 1403/07/07**

Registration timing: **retrospective**

Last update: **2024-09-28, 1403/07/07**

Update count: **0**

Registration date

2024-09-28, 1403/07/07

Registrant information

Name

Muhammad Ahsan Mustafa

Name of organization / entity

CPSP

Country

Pakistan

Phone

+92 333 3396180

Email address

whereisdrahsan@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-01, 1401/03/11

Expected recruitment end date

2023-01-30, 1401/11/10

Actual recruitment start date

2022-01-17, 1400/10/27

Actual recruitment end date

2023-01-15, 1401/10/25

Trial completion date

2023-01-15, 1401/10/25

Scientific title

Comparison of Biliary Leakage between Laparoscopic Versus Open Surgery of Liver Hydatid Cyst: A

Randomized Controlled Trial	
Public title	Comparison of Biliary Leakage between Laparoscopic Versus Open Surgery of Liver Hydatid Cyst: A Randomized Controlled Trial
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Gender; both male and female patients. Age range; 18-60 years. Patients with liver hydatid cyst with size ≥ 3 cm (as per operational definition)
Exclusion criteria:	Severely anemic patients (Hb levels less than 8 g/dl) . Patients with recurrent disease, cysts in liver segment 1 and 7, concomitant cyst in other organs, cysto-biliary communication and patients with ruptured cyst (confirmed from patient record file and any suspected communication will be confirmed on CT) Chronic liver disease (confirmed from patient record file). Alcoholic abuse (patient's history, alcohol consumption for > 1 year) Pregnant ladies
Age	From 18 years old to 60 years old
Gender	Both
Phase	2
Groups that have been masked	Data analyser
Sample size	Target sample size: 84 Actual sample size reached: 84
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization was done using the Random Allocation Software 2.0. Patients were allocated to either group using computer generated sets of random allocation to group A or B. The group allocation was done in advance, and sealed in consecutively numbered opaque envelopes.
Blinding (investigator's opinion)	Single blinded
Blinding description	Statistician was blinded in the study analysis i.e single blinded RCT.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	

1	
Ethics committee	
Name of ethics committee	IRB nishtar medical University
Street address	Nishtar Medical University, Nishtar Rd, Gillani Colony, Multan, Punjab 66000
City	Multan
Postal code	60600
Approval date	2022-06-17, 1401/03/27
Ethics committee reference number	Ref. No. 9652
Health conditions studied	
1	
Description of health condition studied	Echinococcosis, Hydatid disease
ICD-10 code	B67.0
ICD-10 code description	Echinococcus granulosus infection of liver
Primary outcomes	
1	
Description	Biliary leakage
Timepoint	72 hours post-surgery and on follow-up visits at 1, 2, and 4 weeks post-surgery.
Method of measurement	Clinical examination, ultrasonography.
2	
Description	pain
Timepoint	72 hours post-surgery and on follow-up visits at 1, 2, and 4 weeks post-surgery.
Method of measurement	History
3	
Description	recurrence.
Timepoint	72 hours post-surgery and on follow-up visits at 1, 2, and 4 weeks post-surgery.
Method of measurement	Clinical examination, ultrasonography.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group-A: open surgery was done for Hydatid disease

Category

Treatment - Surgery

2

Description

Intervention group- B: laparoscopic surgery for Hydatid disease

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Nishtar Medical University

Full name of responsible person

Dr Khurram Niaz

Street address

Nishtar Medical University, Nishtar Rd, Gillani Colony, Multan, Punjab 66000

City

Multan

Postal code

66000

Phone

+92 321 6801550

Email

Khurram.niaz@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nishtar medical University

Full name of responsible person

Dr Khurram Niaz

Street address

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City

Multan

Postal code

66000

Phone

+92 321 6801550

Email

Khurram.niaz@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Nishtar medical University

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

Sheikh Zayed Medical College

Full name of responsible person

Dr Khurram Niaz

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Khurram Niaz

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Combined Military Hospital Bahawalpur

Full name of responsible person

Muhammad Ahsan Mustafa

Position

Registrar

Latest degree

Bachelor

Other areas of specialty/work

General Surgery

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63100

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Email

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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

Comparison of Biliary Leakage between Laparoscopic
Versus Open Surgery of Liver Hydatid Cyst: A
Randomized Controlled Trial

When the data will become available and for how long

In December 2025

To whom data/document is available

Only available for people working in academic institute

Under which criteria data/document could be used

Khurram.niaz@hotmail.com

From where data/document is obtainable

Khurram.niaz@hotmail.com

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

Through email ID

Comments