Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison ofBiliary 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

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Pakistan

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+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 ofBiliary Leakage between Laparoscopic Versus Open Surgery of Liver Hydatid Cyst: A

Randomized Controlled Trial

Public title
Comparison ofBiliary 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 nishter 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
Nishter Medical University
Full name of responsible person
Dr Khurram Niaz
Street address
Nishtar Medical University, Nishtar Rd, Gillani Colony, Multan, Punjab 66000
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nishter medical University
Full name of responsible person
Dr Khurram Niaz
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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
Nishter 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
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Person responsible for updating data

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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 ofBiliary 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