

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study of the effects of Albendazole therapy(before surgery) on viability of protoscolex

Protocol summary

Study aim

evaluate effect of albendazole on the scoleces viability in hepatic hydatid cyst

Design

clinical trial study with intervention and control groups. community based, simple randomized sampling and blinded outcome assessment.

Settings and conduct

A clinical trial study was conducted to evaluate the therapeutic effect of albendazole on liver hydatid cysts in Mashhad and Imam Reza Hospital. One-way blinding involves a parasitic specialist who performs a sample of cysts.

Participants/Inclusion and exclusion criteria

Patients with hepatic hydatid cyst, whose diagnosis is confirmed by imaging, are included in the study if they are satisfied with the research, and patients who are not satisfied with the study, or who have extrahepatic abdominal hydatid cyst, have pulmonary hydatid cyst or have infectious cysts or who they are related to bile ducts are not included in the study from the beginning.

Intervention groups

Patients are divided into two groups. The first group is given a specific dose of Albendazole for a period of 2 weeks and then undergoes surgery. In the second group, no drugs are prescribed and they are directly subjected to surgery.

Main outcome variables

The use of albendazole for a 2 week period prior to surgery in patients with hepatic hydatid cyst reduces the survival rate of the scoleces in the hydatid cyst.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090124001581N3**

Registration date: **2018-04-24, 1397/02/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-24, 1397/02/04**

Update count: **0**

Registration date

2018-04-24, 1397/02/04

Registrant information

Name

Mohammad Reza Motie

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5255

Email address

motiem@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2015-09-02, 1394/06/11

Expected recruitment end date

2018-09-02, 1397/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of Albendazole therapy(before surgery) on viability of protoscolex

Public title

Effects of Albendazole therapy on liver hydatid cysts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with liver hydatid cyst patients who have not calcified cyst patients with liver hydatid cysts that are not connected with biliary tract patients who have not infected hydatid cyst

Exclusion criteria:

patients who do not want to participate in the study
patients who have contraindication for use of albendazole patients with abdominal and extra hepatic hydatid cyst patients with infected hydatid cyst patients with hydatid cyst that are connected with biliary tracts
patients with calcified hydatid cyst

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was done simple randomly. unit of randomization was individual. In order to balance the number of samples of two groups, the sampling was done using blocking method. The random allocation law was used for limited randomization methods. This method represents a large block for the entire sample size, which means that the balance in the number of people assigned to each of the groups will be at the end of the study. To do this, we first set a total sample size and then randomly assign a set of them to the intervention group and assign the remainder to the control group. In this study, an equal number of balls for the intervention group and the control group are placed in a drawer, and then the balls are randomly recorded without the replacement of the container and the resulting sequence is recorded.

Blinding (investigator's opinion)

Single blinded

Blinding description

the parasitologist specialist who evaluate the hydatid cyst scolex viability in this study has no information about the sample that if the patient had consumed drug or not.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

MAshhad university of medical sciences

Street address

Qoreshi building, Daneshgah avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2015-09-02, 1394/06/11

Ethics committee reference number

IR.MUMS.FM.REC.1394.216

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

scolex viability

Timepoint

After intervention

Method of measurement

Permeability method with eosin

Secondary outcomes

empty

Intervention groups

1

Description

There is no drug administration for control group

Category

Treatment - Drugs

2

Description

administration of Albendazole 1.5 mg/kg/day for a period of 7 days for intervention group2

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Mohammad Reza Motie

Street address

Imam Reza Hospital

City

Mahshad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3858 3834

Email

motiem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Second floor of ghorshi building, Daneshgah st.

City

Mashhad

Province

Razavi Khorasan

Postal code

951-91735

Email

motiem@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Motie

Position

Associated proffesor of surgery

Latest degree

Specialist

Other areas of specialty/work

Street address

Imam Reza hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2664

Fax

Email

motiem@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Surgical Oncology Research center, Mashhad
University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Motie

Position

Associated Proffesor of Surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam Reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2664

Fax

Email

motiem@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Ali Vahidi Rad

Position

Surgery Assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Imam reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2664

Fax**Email**

vahidirada931@mums.ac.ir

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available