

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 group 2

#### 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

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**Postal code**

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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**

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**Province**

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**Postal code**

9137913316

**Phone**

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**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