Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 51 3852 5255

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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 billiary 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 hydatis cyst patients with infected hydatid cyst patients with hydatid cyst that are connected with biliary tracts patients with calcified hydatis 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 hydatis 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
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Mashhad
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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 of7 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Person responsible for updating data

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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