

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Clinical efficacy of the essence oil of *Zartaria multiflora* on human liver hydatid cyst in comparison with Albendazole

Protocol summary

Study aim

To evaluate the efficacy of *Z. multiflora* essential oil (EO) against hepatic CE in comparison with albendazole.

Design

In this non randomized clinical study, 30 patients were divided into two groups and were treated with *Z. multiflora* essential oil and albendazole respectively. Since the patients were allowed to select their favorite drug (Albendazole or *Z. multiflora* essential oil), random distribution of the patients in two treatment groups was not feasible.

Settings and conduct

This non randomized clinical study was performed at Shiraz University of Medical Sciences (Shahid Faghihi Hospital) and Shiraz University, Shiraz, Iran.

Participants/Inclusion and exclusion criteria

1. Patients who accept the treatment protocol by signing the appropriate informed consent. 2. Patients aged 20 - 60 years old. 3. Patients with hepatic hydatid cysts smaller than 5 cm. 4. Patients with uncomplicated hydatid cysts (non calcified and non infected cysts). 5. Patients who were not simultaneously infected to pulmonary hydatid disease.

Intervention groups

30 patients, were divided into two groups (15 in each) and treated for 6 months (180 consecutive days) with *Zartaria multiflora* essential oil (60 mg daily) and albendazole (800 mg daily) respectively. *Z. multiflora* essential oil soft capsules were produced by Barij Essence Pharmaceutical Company, Iran and albendazole tablets were produced by CIPLA LTD, India. Before the start of treatment and 2, 4 and 6 months after treatment, the size of the cysts were measured by sonography. Simultaneously, biochemical and hematological analysis were performed on the blood samples of patients. At the end of study, the mean size of the cysts and the results of the liver and kidney function tests were compared statistically between the patients of two treatment groups.

Main outcome variables

Reduction in the size of hydatid cysts.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180219038798N1**

Registration date: **2018-08-06, 1397/05/15**

Registration timing: **retrospective**

Last update: **2018-08-06, 1397/05/15**

Update count: **0**

Registration date

2018-08-06, 1397/05/15

Registrant information

Name

Mohammad Moazeni

Name of organization / entity

Shiraz University

Country

Iran (Islamic Republic of)

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+98 71 3613 8676

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

2015-04-12, 1394/01/23

Actual recruitment end date

2017-09-05, 1396/06/14
Trial completion date
empty

Scientific title
Clinical efficacy of the essence oil of Zartaria multiflora on human liver hydatid cyst in comparison with Albendazole

Public title
Clinical efficacy of the essence oil of Zartaria multiflora on human liver hydatid cyst

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who accepted the treatment protocol by signing the appropriate informed consent, Patients with hepatic hydatid cysts smaller than 5 cm, Patients with uncomplicated hydatid cysts (non calcified and non infected to bacterial infections), Patients who were not simultaneously infected to pulmonary hydatid disease
Exclusion criteria:
Refusal of treatment at each stage of the treatment period Patients with symptoms of complicated cysts (infection, abscessation). Enlargement of the cysts during the course of treatment. Adverse drug reactions leading to discontinuation of the treatment Patients who don't refer for periodic examinations and necessary tests
Recurrence of the disease

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

14336 - 71348

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.Sums.Rec.1396.335

Health conditions studied

1

Description of health condition studied

Hydatid disease (Hydatid cyst)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduction in the size of hydatid cysts

Timepoint

Before the start of treatment and after all treatment periods (totally 4 times)

Method of measurement

By sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 15 patients consumed orally the 20 mg soft capsules of Zataria multiflora essential oil (produced by Barij Essence Pharmaceutical Company, Iran) 3 times a day for 6 months (180 consecutive days). Before the start of treatment and 2, 4 and 6 months after the start of treatment, the size of the cysts were measured by sonography. Simultaneously, biochemical and hematological analysis was performed on the blood samples of patients to assess the possible side effects. At the end of study, the mean size of the cysts and the results of the liver and kidney function tests were compared statistically between the patients of two treatment groups.

Category

Treatment - Drugs

2

Description

Control group: The patients of this group (15 patients) consumed orally the 400 mg tablets of albendazole (produced by CIPLA LTD, India) 2 times a day for 6 months. All measurements and tests were performed exactly as in the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Dr. Hajar Khazraei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University

Full name of responsible person

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Street address

Bajgah area, School of Veterinary Medicine

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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

Shiraz 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

Shiraz University

Full name of responsible person

Dr. Mohammad Moazeni

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Parasitology

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Full name of responsible person

Dr. Mohammad Moazeni

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Parasitology

Street address

Bajgah area, School of Veterinary Medicine

City

Shiraz

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

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable