

# 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)

##### Phone

+98 71 3613 8676

##### Email address

moazeni@shirazu.ac.ir

##### 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

##### Street address

Zand street

##### City

Shiraz

##### Province

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##### Postal code

44119 - 71348

##### Phone

+98 71 3235 1087

##### Fax

+98 71 3233 1634

##### Email

khazraee@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University

##### Full name of responsible person

Dr. Mohammad Moazeni

##### Street address

Bajgah area, School of Veterinary Medicine

##### City

Shiraz

##### Province

Fars

##### Postal code

71441-69155

##### Phone

+98 71 3228 6950

##### Fax

+98 71 3228 6940

##### Email

moazeni@shirazu.ac.ir

##### Web page address

<http://shirazu.ac.ir/vet/>

##### 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

#### Street address

Bajgah area< School of Veterinary Medicine

#### City

Shiraz

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## Person responsible for scientific 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 updating data

**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

**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