

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **Determination of the efficacy of cryotherapy plus topical *Juniperus excelsa* M.Bieb, based on traditional Persian medicine, versus cryotherapy alone in the treatment of cutaneous leishmaniasis: a double-blind randomized clinical trial**

#### **Protocol summary**

##### **Study aim**

Determination of the efficacy of cryotherapy plus topical *Juniperus excelsa* M.Bieb, based on traditional Persian medicine, versus cryotherapy alone in the treatment of cutaneous leishmaniasis

##### **Design**

Two arm parallel group randomised clinical trial, triple-blinded

##### **Settings and conduct**

Design of the study: Patients with cutaneous leishmaniasis lesions referring to Shohaday-e- Enghelab Health Center of Shiraz and Shahid Faghihi Dermatology Clinic. In order to blind the researcher, medications are named as "A" for 5% *Juniperus excelsa* M.Bieb cream and B for placebo. The patient don't aware of the type of drug he/she is assigned to. In addition, the groups are entered into statistical analysis as "A" and "B".

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: 1- Age 18 to 70 years the maximum 2- The maximum duration of their involvement by leishmaniasis is 4 months 3- Having physical health except the cutaneous leishmaniasis infection 4- Having 4 or less of the lesion leishmaniasis lesions 5- Did not taking any of topical and systemic anti-Leishmania treatment during last 4 weeks 6- Cutaneous leishmaniasis is approved of by smear\*\*\*\* Exclusion criteria: 1- Patients with complex forms of leishmaniasis and symptoms of mucousal leishmaniasis 2- Having more than 4 lesions 3- The lesions greater than 5 cm 4- Sub-cutaneous nodules 5- Regional adenopathy if greater than 1 cm size 6- Patients with immunodeficiency disease 7- The infants and children less than 18 years 8- Women in lactation and pregnancy 9- Patients with satellite lesions or sporotrichoid lesions 10- Patients with facial cutaneous leishmaniasis lesions

##### **Intervention groups**

Group A: Use of topical product (5% extract of *Juniperus excelsa* M.Bieb leaf cream) on cutaneous leishmaniasis lesions, 3 times daily Group B: Use of Placebo cutaneous leishmaniasis lesions, 3 times daily

##### **Main outcome variables**

The area of the cutaneous leishmaniasis lesions of the patients

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT2015082523753N1**

Registration date: **2015-09-05, 1394/06/14**

Registration timing: **prospective**

Last update: **2018-02-17, 1396/11/28**

Update count: **1**

##### **Registration date**

2015-09-05, 1394/06/14

##### **Registrant information**

##### **Name**

Mohammad Mahdi Parvizi

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 71 3212 5592

##### **Email address**

parvizim@sums.ac.ir

##### **Recruitment status**

##### **Recruitment complete**

##### **Funding source**

Vice chancellor of Research, Shiraz University of Medical Sciences

**Expected recruitment start date**

2015-10-07, 1394/07/15

**Expected recruitment end date**

2016-03-20, 1395/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Determination of the efficacy of cryotherapy plus topical Juniperus excelsa M.Bieb, based on traditional Persian medicine, versus cryotherapy alone in the treatment of cutaneous leishmaniasis: a double-blind randomized clinical trial

**Public title**

Effectiveness of traditional medicine products Juniperus excelsa M.Bieb in the treatment of cutaneous leishmaniasis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 to 70 years the maximum The maximum duration of their involvement by leishmaniasis is 4 months Having physical health except the cutaneous leishmaniasis infection Having 4 or less of the lesion leishmaniasis lesions Did not taking any of topical and systemic anti-Leishmania treatment during last 4 weeks Cutaneous leishmaniasis is approved of by smear

**Exclusion criteria:**

Patients with complex forms of leishmaniasis and symptoms of mucousal leishmaniasis Having more than 4 lesions The lesions greater than 5 cm Sub-cutaneous nodules Regional adenopathy if greater than 1 cm size Patients with immunodeficiency disease The infants and children less than 18 years Women in lactation and pregnancy Patients with satellite lesions or sporotrichoid lesions Patients with facial cutaneous leishmaniasis lesions

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation software Ink was used to create a randomization table

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In order to blind the investigator, medications are named A (Juniperus excelsa) and B (Placebo). The patient are not considered the type of drug are assigned to. The groups are also coded A and B for statistical analyzes.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

invivo and invitro phase of the study has been completed and now this study is carried out the effects of drugs on humans, .

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences, Zand blv., Shiraz, Fars, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

14336 - 71348

**Approval date**

2015-08-23, 1394/06/01

**Ethics committee reference number**

IR.SUMS.REC.1394.91

**Health conditions studied****1****Description of health condition studied**

cutaneous leishmaniasis

**ICD-10 code**

B55.1

**ICD-10 code description**

Cutaneous leishmaniasis

**Primary outcomes****1****Description**

size and area of leishmaniasis lesion

**Timepoint**

previous of the starting the treatment, weekly in the first month of treatment and every two weeks from second

month to the end of the study

#### Method of measurement

Cooley and math with the square millimeters

## Secondary outcomes

### 1

#### Description

Duration of the healing the lesion

#### Timepoint

At the end of the treatment process

#### Method of measurement

The time interval between the beginning and end of treatment in days

## Intervention groups

### 1

#### Description

Intervention group: cryotherapy as a standard treatment in addition to cream (topical pharmaceutical products) containing 5% extract of *Juniperus excelsa* M.Bieb administrate, three times daily for 12 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

control group: cryotherapy as a standard treatment in addition to topical placebo cream with drug-like compounds and color with the exception of *Juniperus excelsa* M.Bieb extract, administrate every 8 hours daily for 12 weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology clinic of Shahid Faghihi hospital

##### Full name of responsible person

Mohammad Mahdi Parvizi, MD, PHD

##### Street address

Shahid Faghihi hospital, Zand blv., Shiraz, Fars, Iran

##### City

Shiraz

##### Province

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7134844119

##### Phone

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##### Email

mmparvizi@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Enghelab Health center of Shiraz

##### Full name of responsible person

Mohammad Mahdi Parvizi, MD, PHD

##### Street address

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Seyd Basir Hashemi, MD

##### Street address

7th floor, Vice Chancellor of Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

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#### Grant name

محل پرداخت قراردادهای دانشگاه علوم پزشکی شیراز

#### Grant code / Reference number

94-7556

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

Yes

#### Title of funding source

Shiraz 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**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Dr. Mohammad Mahdi Parvizi

**Position**  
PHD Student of traditional Persian medicine

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Traditional Medicine

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## Person responsible for scientific inquiries

### Contact

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Dr. Farhad Handjani,

**Position**  
Associate professor of Dermatology

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Specialist

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Dermatology

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## Person responsible for updating data

### Contact

### Name of organization / entity

Shiraz University of Medical Sciences

**Full name of responsible person**  
Dr. Mohammad Mahdi Parvizi

**Position**  
PHD Student of traditional Persian medicine

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Traditional Medicine

**Street address**  
7th floor, building No.2, School of Medical Science,  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

The characteristics of the patients participating in the study is reported in the published article.

### When the data will become available and for how long

The documentation had been published on PLOS Neglected Tropical Diseases journal's website .

### To whom data/document is available

All of the researchers

### Under which criteria data/document could be used

Provided that cite to the article if the data and results of this study are used

### From where data/document is obtainable

PLOS Neglected Tropical Diseases journal's website

### What processes are involved for a request to access data/document

visit the PLOS Neglected Tropical Diseases journal's website and also sending a request via the email to the researchers

### Comments

