

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Fars

Postal code

7134844119

Phone

+98 71 3212 5592

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

Siouye blv. Enghelab Health center of Shiraz

City

Shiraz

Province

Fars

Postal code

7164788363

Phone

+98 71 3738 7735

Email

mmparvizi@gmail.com

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

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

vcrdep@sums.ac.ir

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

Street address

7th floor, building No.2, School of Medical Science,
Zand blv, Shiraz, Fars, Iran

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 7966

Fax**Email**

mmparvizi@gmail.com

Web page address**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,
Zand blv, Shiraz, Fars, Iran

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3234 7966

Fax**Email**

mmparvizi@gmail.com

Web page address

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Farhad Handjani,

Position

Associate professor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Dermatology department of Shahid Faghihi Hospital,
Zand blv. Shiraz, Fars, Iran

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3231 9049

Fax**Email**

hanjanif@yahoo.com

Web page address

Person responsible for updating data

Contact

