Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 adenopaty 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)

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+98 71 3212 5592

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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 adenopaty 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 proccess

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 adminnistrate, 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

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2

Recruitment center

Name of recruitment center

Enghelab Health center of Shiraz

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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
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Position
PHD Student of traditional Persian medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 charasrristic 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 thedata 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