

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Study of standard treatment of cutaneous leishmaniasis (cryotherapy) in comparison to a traditional herbal remedy

Protocol summary

Summary

The purpose of this study is the comparison of standard treatment of cutaneous leishmaniasis (cryotherapy) to a traditional herbal remedy. Eighty eight patients (2 groups of 44 patients) with positive direct smear of cutaneous leishmaniasis, number of scars less than 3 and disease period less than 3 months will be entered in to the study. Wounds size will be monitored weekly for one month in the 2 mentioned groups: 1st group treated with daily 10 grams of herbal medicine while, 2nd group would be treated with 10-20 sec cryotherapy weekly for one month period of time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011512143N1**

Registration date: **2013-02-07, 1391/11/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-07, 1391/11/19

Registrant information

Name

Abdolali Mohagheghzadeh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1242 4256

Email address

mohaghegh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Health system of Shiraz University of Medical Sciences

Expected recruitment start date

2013-01-29, 1391/11/10

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of standard treatment of cutaneous leishmaniasis (cryotherapy) in comparison to a traditional herbal remedy

Public title

herbal medicine in cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: number of wound less than 3; disease period less than 3 months; without previous treatment; without systemic or other skin disease Exclusion criteria: hypersensitivity to herbal medicine; pregnancy and etc

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

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**

Shiraz University of Medical Sciences

Street address

Zand Blvd, Shiraz

City

Shiraz

Postal code**Approval date**

2013-01-07, 1391/10/18

Ethics committee reference number

CT-91-6414

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

Leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

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

complete treatment of Wound

Timepoint

before treatment, 1,2,3,4 weeks after treatment

Method of measurement

measurement of Wound size

Secondary outcomes**1****Description**

adverse effect

Timepoint

before treatment, 1,2,3,4 weeks after treatment

Method of measurement

question from patient

Intervention groups**1****Description**

treatment with daily 10 grams of herbal medicine for one month.

Category

Treatment - Drugs

2**Description**

treatment with 10-20 Seconds cryotherapy for one month.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health system of Shiraz University of Medical Sciences

Full name of responsible person

Alireza Barzegar

Street address

Zand Blvd. Shiraz

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Shiraz University of Medical Sciences

Street address

Zand Blvd. Shiraz

City

Shiraz

Grant name**Grant code / Reference number****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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Hatam

Position

Professor

Other areas of specialty/work**Street address**

Zand Blvd. Shiraz

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hatamghr@sums.ac.ir

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Alireza Barzegar

Position

student

Other areas of specialty/work**Street address**

Shiraz School of Pharmacy

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barzegarar@sums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Abdolali Mohagheghzadeh

Position

Professor

Other areas of specialty/work**Street address**

Traditional pharmacy department, Shiraz School of Pharmacy

City

Shiraz

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty