Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 comparition 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 entered in to the study. Wounds size will monitored weekly for one month in the 2 mentioned groups: 1 st group treated with daily 10 grams of herbal medicine while, 2 nd group would treat 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)
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+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
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Professor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
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Person responsible for updating data

Contact
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Alireza Barzegar
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student
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Web page address

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