Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy of topical nitric oxide 3% and cryotherapy with cryotherapy and placebo in cutaneous leishmaniasis

Protocol summary

Summary

Cutaneous leishmaniasis is a protozoan disease with an annual incidence of almost 2 million new cases worldwide making it one of the most common infectious diseases globally. To compare the effect of topical nitric oxide 3% and Cryotherapy with Cryotherapy and placebo in the treatment of cutaneous leishmaniasis, 100 patients (50 patients in each group) with cutaneous leishmaniasis were randomized to receive either topical nitric oxide3% and cryotherapy or cryotherapy and placebo for 12 weeks. Patients received cryotherapy once a week and topical nitric oxide or placebo three times a day. They were visited every other week for evaluation of response rate with measuring the diameters of the largest lesion and probable side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710191535N1**
Registration date: **2009-07-05, 1388/04/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-07-05, 1388/04/14

Registrant information

Name

Farideh Dehghani

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 77 1230 5410

Email address

dehghanifa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2007-09-20, 1386/06/29

Expected recruitment end date

2009-02-20, 1387/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of topical nitric oxide 3% and cryotherapy with cryotherapy and placebo in cutaneous leishmaniasis

Public title

Evaluation of efficacy of topical nitric oxide in treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age more than 12 years, less than 5 active lesion, no topical treatment from 2 weeks prior to study and no systemic treatment from 1 month prior to study, Exclusion criteria: pregnancy and lactation, facial lesions, lesions with more than 4 months duration

Age

From **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Science
Street address
Karim Khan Zand Boulevard.
City
Shiraz
Postal code
7134844119
Approval date
2007-04-09, 1386/01/20
Ethics committee reference number
ct-86-3665

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
Complete improvement
Timepoint
Baseline, every other week
Method of measurement
measurment of erythema and induration diameter with a ruler

Secondary outcomes

1

Description
Side effects
Timepoint
every other week
Method of measurement
medical history taking and physical examination

Intervention groups

1

Description
Intervention: topical nitric oxide 3 percent 3 times a day + cryotherapy once a week for 12 weeks
Category
Treatment - Drugs

2

Description
Control: placebo cream 3 times a day + cryotherapy once a week for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital, dermatology clinic
Full name of responsible person
Farideh Jowkar, MD.
Street address
Shahid Faghihi hospital, Karimkhan Zand Boulevard
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hosein Dabaghmanesh,MD
Street address
Karim Khan Zand Boulevard, Shiraz University of Medical Sciences
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 Science

Full name of responsible person

Farideh Dehghani,MD

Position

Resident of dermatology

Other areas of specialty/work

Street address

Dermatology clinic, Shahid Faghihi Hospital, Karim khan Zand Boulevard

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Farideh Jowkar,MD

Position

Dermatologist, Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farideh dehghani,MD

Position

Resident of dermatology

Other areas of specialty/work

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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