

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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 oxide 3% 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

measurement 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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+98 71 1235 1087

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farideh.dehghani@yahoo.com

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## Person responsible for scientific inquiries

**Contact**

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**Position**

Dermatologist, Assistant Professor

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## Person responsible for updating data

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Shiraz University of Medical Sciences

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**Position**

Resident of dermatology

**Other areas of specialty/work**

**Street address**

Dermatology clinic, Shahid Faghihi Hospital, Karim  
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**Email**

farideh.dehghani@yahoo.com

**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*