

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between the efficacy of intralesional placebo and nitric oxide releasing patch versus placebo patch and glucantime in the treatment of cutaneous leishmaniasis

Protocol summary

Summary

The aim of this study is to determine the effects of nitric oxide released by nitroglycerin patch and intralesional injection of placebo (distilled water) versus placebo patch with intralesional glucantime injection in the treatment of acute cutaneous leishmaniasis. This study is a Randomized, double-blind (both of patient and physician will be unaware), placebo controlled clinical trial and is done in Skin Diseases and Leishmaniasis Research Center, Sedigheh Tahereh Hospital. Inclusion Criteria: Patients must be 18-50 age In the clinical phase of the study, 104 lesions of participants will be randomly divided to two treatment groups by Randomized Allocation software. Fifty two Lesions of patients will be treated with intralesional injection of placebo and nitroglycerin patch and 52 lesions of patients will be treated with topical treatment included nitroglycerin patch and intralesional injections of glucantime. All patients will be similar in relative conditions in both groups. The questionnaire is provided for patients that whole characteristics of patients and measured size of the lesions will be recorded in it. So the induration of lesions is characterized. The first group will be treated with weekly intralesional injections of placebo up to 8 weeks to recover damages associated with nitroglycerin patch. The second group, weekly Glucantime injections plus placebo nitroglycerin is used one time in day for 8 weeks until complete cure. Then, patients will be evaluated regularly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904091159N7**

Registration date: **2013-09-02, 1392/06/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-02, 1392/06/11

Registrant information

Name

Mohamad Ali Nilforoushzadeh

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 21 2220 5158

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the efficacy of intralesional placebo and nitric oxide releasing patch versus placebo patch and glucantime in the treatment of cutaneous leishmaniasis

Public title

Comparison between two groups in the treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Patients with a diagnosis of acute zoonotic cutaneous leishmaniasis has been proven parasitology by direct smear 2- Patients must be 18-50 age 3- Lesion diameter is not greater than 3 cm 4- The number of lesion is one 5- Lesions are not on the face near the eyes, joints, cartilage, on the nose and ears 6- Less than three months passed from diseases times. Exclusion Criteria: 1- The status of women in pregnancy and lactation 2- The risk of presence or incidence of sporotrichoid or Satellite lesions 3- Patients with a history of hepatitis, heart and kidney disorder 4- People who are taking immunosuppressive medications (over the last 6 months) 5- history of local or systemic treatment against leishmaniasis in the last 3 months 6- Patients with a history of heart attack or high blood pressure 7- Liver disease 8- Patients with anemia 9- Patients with a history of surgery for head and brain hemorrhage 10- Patients with blood pressure medications, antidepressants, or drugs used for angina.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

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**

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Enghelab Street, Tehran, Iran

City

Tehran

Postal code**Approval date**

2012-12-22, 1391/10/02

Ethics committee reference number

72308

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

Cutaneous leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis (any type)

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

Lesion area

Timepoint

8, 12, 20 weeks after end of treatment

Method of measurement

Pictzar software

2**Description**

Induration

Timepoint

1, 2, 3, 4, 7, 8, 12, 16, 20 weeks after end of treatment

Method of measurement

Physical examination

3**Description**

Improvement rate

Timepoint

1, 2, 3, 4, 7, 8 weeks during treatment and 12, 16, 20 weeks after end of treatment

Method of measurement

Observation and examination

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

Side effects

Timepoint

3 months after treatment

Method of measurement

Observation and examination

Intervention groups

1

Description

Treatment of Nitroglycerin patch(the pharmacy of Nour and Ali Asghar hospital in Isfahan) 1 time every day covered nearly 2-3 inch of lesion + interlesional injection of placebo (injection of distilled water) 1 time every week nearly 15-30 mg until whitening of base of the ulcer during of 8 weeks until complete cure

Category

Treatment - Other

2

Description

Interlesional injection of Glucantime(Meglusan) from Avenue de Scheut company in Belgica, 1 time every week, nearly 15-30 mg until whitening of base of the ulcer + treatment of placebo patch(the pharmacy of Nour and Ali Asghar hospital in Isfahan) 1 time every day covered nearly 2-3 inch of lesion during 8 weeks until complete cure

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin Diseases and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Isfahan, Ir

Full name of responsible person

Leila Shirani Bidabadi

Street address

Skin Diseases and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Sedigheh Tahereh (AS) Research Centers Complex, Khorram Ave., Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Vice chancellor for research, Tehran University of Medical Sciences, Enghelab Street, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Skin Diseases and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Isfahan, Ir

Full name of responsible person

Leila Shirani Bidabadi

Position

MSc

Other areas of specialty/work

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Full name of responsible person

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Position

Associate Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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