Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 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
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Iran (Islamic Republic of)
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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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Person responsible for scientific inquiries

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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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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