

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

investigation of the therapeutic effects of intralesional injection of Nimodipine on the treatment of resistant cases of cutaneous leishmaniasis

Protocol summary

Study aim

Determination of the therapeutic effects of intralesional injection of Nimodipine on the treatment of resistant cases of cutaneous leishmaniasis

Design

This study is a clinical trial conducted without blinding and control group on 17 patients with leishmaniasis who are resistant to treatment

Settings and conduct

The study is conducted on patients referring to dermatology clinic of Ghaem hospital in Mashhad. The amount of Nimodipine medication required for intralesional is 30 µg / ml, and given that the vials of Nimodipine are 10 mg per 50 cc and each cc contains 200 µg, each vial is diluted 6 times with normal saline and each lesion is injected with up to a maximum of 1 cc

Participants/Inclusion and exclusion criteria

Inclusion criteria : age more than 18 years, maximum lesion number of 4; duration of illness is less than one year, lesion type is dry Leishmaniasis; Exclusion criteria : having other atypical forms, patients who have had a heart attack within the last month, patients with unstable angina, use of medications such as Azoles and Sodium Vauproat, Macrolide and Fluoxetine, incidence of drug complications during treatment; pregnancy, breastfeeding, the lesion is preferably not on the face

Intervention groups

Intervention group: Patients who have got a complete treatment period with intralesional glucantime injections and have resistance to treatment (no clinical improvement of lesions after 12 sessions of injection) enter the study through convenience sampling. These patients receive weekly intralesional injection of Nimodipine for 10 weeks as treatment.

Main outcome variables

size of lesion and induration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160215026563N2**

Registration date: **2019-01-14, 1397/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-14, 1397/10/24**

Update count: **0**

Registration date

2019-01-14, 1397/10/24

Registrant information

Name

Mohammad Javad Yazdanpanah

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2851

Email address

yazdanpanahmj@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-27, 1397/04/06

Expected recruitment end date

2020-06-26, 1399/04/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
investigation of the therapeutic effects of intralesional injection of Nimodipine on the treatment of resistant cases of cutaneous leishmaniasis

Public title
Investigation of the effect of Nimodipine on the treatment of resistant cutaneous leishmaniasis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 18 years; maximum lesion number is 4; duration of illness is less than one year; lesion type is dry Leishmaniasis (Clinical manifestation of urban leishmaniasis); There are no signs of lymphangitis and sporotrichoid; No more than 2 months has passed from the incidence of the lesion until wound formation; there is no widespread wound and secretion.
Exclusion criteria:
having other atypical forms such as lupoid-sporotrichoid-erysipeloid-zoster forms and....; patients who have had a heart attack within the last month; patients with unstable angina; patients with less than 100 spontaneous bacterial peritonitis (SBP) and consuming medications such as Azoles and Sodium Valproate, and Macrolide and Fluoxetine due to the prohibition of Nimodipine use in these people; incidence of drug complications during treatment such as Phlebitis, hypotension, headache, severe nausea and vomiting; pregnancy; breastfeeding; the lesion is preferably not on the face.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **17**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Approval date
2018-04-11, 1397/01/22
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.230

Health conditions studied

1

Description of health condition studied
resistant cases of cutaneous leishmaniasis
ICD-10 code
B55.1
ICD-10 code description
Cutaneous leishmaniasis

Primary outcomes

1

Description
Change in size and value of induration
Timepoint
Patients are evaluated every week until the end of treatment, one and a half months and three months after the end of the treatment.
Method of measurement
Using caliper and measuring the diameter of lesion

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who have had a complete treatment period with intralesional glucantime injections and have resistance to treatment (no clinical improvement of lesions after 12 sessions of injection) enter the study through convenience sampling. These patients receive weekly intramuscular injection of Nimodipine for 10 weeks as treatment. The amount of medication required for intralesional injection is 30 µg / ml.

Category

Treatment - Drugs

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem hospital

Full name of responsible person

Marzieh Pishgouy

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Ghaem hospital, Ahmad Abad Ave

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Marzieh Pishgouy

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Mohammad Javad Yazdanpanah

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments