Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Nomidipine medication required for intralesional is 30 µg / ml, and given that the vials of Nomidipine 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)

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+98 51 3801 2851

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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 sings 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 Vauproat, 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

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Marzieh Pishgouy
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Sponsors / Funding sources

1

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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
Country of origin
Type of organization providing the funding
Academic

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
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Person responsible for updating data

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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