

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Investigation of the therapeutic effect of diphencyprone induced local hypersensitivity on treatment of acute urban leishmaniasis with intralesional injection of glucantime

Protocol summary

Study aim

Investigation of the therapeutic effect of diphencyprone induced local hypersensitivity in treatment of acute leishmaniasis

Design

This clinical trial has a control group, is randomized through a list of random numbers by a computer, with parallel groups and is carried out without blinding.

Settings and conduct

No blinding is done in this study and it will be performed on patients with acute leishmaniasis referring to Imam Reza Hospital of Mashhad. Patients will be observed at the onset of treatment and then weekly up to 12 weeks and size of lesions using a ruler in both groups, the complications and response to treatment and the time required for treatment will be recorded in each session.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Positive direct smear or biopsy of the lesion in terms of Leishman body, lesion in limbs, dry leishmaniasis, patient has an indication of topical treatment, a maximum of 6 months has elapsed since the onset of the lesion. Exclusion Criteria: Sensitivity to intralesional glucantime, presence of secondary infection in the lesion, pregnancy or breastfeeding

Intervention groups

Control group: Patients will undergo treatment with intralesional glucantime (produced by the French company Sanofi) weekly. Intervention group: At the same time as intralesional injection of glucantime, after sensitization with 2% diafenecprone (produced by the American company Sigma) solution on the upper arm, increasing doses of diphencyprone will be used weekly up to the development of eczema and weakly treatment will continue until complete recovery with a sensitization dose.

Main outcome variables

rate of recovery in both groups, the time required for the

lesions to heal

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140414017271N6**

Registration date: **2019-02-17, 1397/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-17, 1397/11/28**

Update count: **0**

Registration date

2019-02-17, 1397/11/28

Registrant information

Name

Yalda Nahidi

Name of organization / entity

department of dermatology, Ebne Sina St, Imam Reza hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 1802 2490

Email address

nahidiy@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the therapeutic effect of diphencyprone induced local hypersensitivity on treatment of acute urban leishmaniasis with intralesional injection of glucantime

Public title

Investigation of the effect of diphencyprone on treatment of acute urban leishmaniasis with intralesional injection of glucantime

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Positive smear or biopsy of the lesion in terms of Leishman body Lesion in limbs dry leishmaniasis The patient has an indication of topical treatment based on the judgment of the therapist and the national protocol for leishmania A maximum of 6 months has elapsed since the onset of the lesion The patient has an informed consent to participate in the study.

Exclusion criteria:

Sensitivity to intralesional injection of glucantime The presence of secondary infection in the lesion based on the researcher's judgment Pregnancy or breastfeeding Wet leishmaniasis, Lupoid, Sporotricoid

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **44****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization is done through the random allocation list by PASS software.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

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

9138813944

Approval date

2017-02-08, 1395/11/20

Ethics committee reference number

IR.MUMS.fm.REC.1395.550

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**

The rate of recovery in the two groups

Timepoint

Every week after the injection up to 12 weeks

Method of measurement

Size of the lesions will be recorded using a ruler and stiffness and induration will also be recorded based on examination in each session.

2**Description**

The amount of time needed for the lesions to heal

Timepoint

Every week until lesion recovery

Method of measurement

Based on the number of weeks passed until recovery

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: At the same time as intralesional injection of glucantime, after sensitization with 2% diphencyprone (produced by the American corporation Sigma) solution on the upper arm, increasing doses of diphencyprone will be used weekly up to the development of eczema (erythema and itching for at least 2 days) and weakly treatment will continue until complete recovery with a sensitization dose.

Category

Treatment - Drugs

2

Description

Control group: Patients undergoing intralesional injection of glucantime (produced by the French corporation Sanofi) will continue treatment weekly until complete recovery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Imam Raza Hospital

Full name of responsible person

Faeze Taghavi

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Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue

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2

Recruitment center

Name of recruitment center

Dermatology clinic, Ghaem Hospital

Full name of responsible person

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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

950517

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

Faeze Taghavi

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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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

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

Data analysis 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