

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of combined intralesional injection of glucantime and interferon gamma with intralesional glucantime alone in the treatment of cutaneous leishmaniasis

Protocol summary

Summary

The purpose of this study is evaluation of adding INF gamma to standard treatment for cutaneous leishmaniasis. Fifty patients with cutaneous leishmaniasis referred in Ghaem and Emam Reza hospitals, that they have not received any treatment for their disease in last two months and have treatment with intralesional meglumine, will be selected, and will be divided to 2 Groups of 25 people, control and intervention. In the intervention group, glucantime and interferon gamma and in control just glucantime will be injected. Characteristics including age, gender, duration of the injury, the biggest diameter of the induration and the place of injury will be recorded. The patients in terms of the rate of healing, based on the change in the induration size, will be divided into 3 groups: full healing, significant healing and active lesions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012420740N2**

Registration date: **2015-10-21, 1394/07/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-21, 1394/07/29

Registrant information

Name

Fakhrozaman Pezeshkpoor

Name of organization / entity

Mashhad University of Medical Sciences, Ghaem Hospital

Country

Iran (Islamic Republic of)

Phone

+98 38012861

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pezeshkpoorf@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Skin Diseases and Leishmaniasis Research Center, Mashhad University of Medical Sciences, School of Medicine

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of combined intralesional injection of glucantime and interferon gamma with intralesional glucantime alone in the treatment of cutaneous leishmaniasis

Public title

Comparison of combined intralesional injection of glucantime and interferon gamma with intralesional glucantime alone in the treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterias: Positive smear or biopsy of the lesion

in terms of Amastigotes; Not sensitivity to glucantime; The patient who has indications of topical treatment based on state protocol; Less than one year past from onset of the illness; No treatment is received in at least 2 months; Not pregnant and not lactating; The patient is willing to participate in the study. exclusion criterias: No have regular visit; Secondary infection of the lesion based on clinical features and judging therapist; Use of other medications during the study.

Age

From **18 years** old to **139 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University

Street address

Central Building of Mashhad University of Medical Sciences (Ghoreishi), Daneshgah 16, Daneshgah Street, Mashhad, Khorasan Razavi, Iran, Islamic Republic Of

City

Mashhad

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

920211

Health conditions studied

1

Description of health condition studied

Cutaneous Leishmaniasis

ICD-10 code

B50,B51,B5

ICD-10 code description

Protozoal diseases

Primary outcomes

1

Description

The rate of healing

Timepoint

Once a week up to 12 weeks after treatment

Method of measurement

Outcomes based on the percent reduction of induration: full healing (100% healing), significant healing (75%> reduce induration), relatively healing (50-75% reduce induration), low healing (25-50% reduce induration), no response (25%< reduce induration)

Secondary outcomes

1

Description

Treatment effects

Timepoint

Once a week up to 12 weeks after treatment

Method of measurement

Local or systemic clinical reactions cause of using drugs

Intervention groups

1

Description

intervention: Injection of interferon gamma with standard treatment (Injection of Glucantime). control: Glucantime standard drug.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Street address

City

Mashhad

2

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Street address

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences, Vice
Chancellor for Research

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical
Sciences (Ghorshi), Daneshgah 16, Daneshgah Street,
Mashhad, Khorasan Razavi, Iran, Islamic Republic Of

City

Mashhad

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, Vice Chancellor
for Research

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

Mashhad University of Medical Sciences

Full name of responsible person

Fakhrozaman Pezeshkpoor

Position

PHD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Other areas of specialty/work

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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