# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 reffered 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

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**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
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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, 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
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PHD
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*