# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Study of the additional effect of topical ciprofloxacin on intralesional injection of glucantime in the treatment of cutaneous leismaniasis

### Protocol summary

**Study aim**
Study of the additional effect of topical ciprofloxacin on intralesional injection of glucantime in the treatment of cutaneous leismaniasis

**Design**
This study is a randomized controlled trial study of phase three with parallel groups performed on two groups of 26 patients with anterior leishmaniasis. Random allocation software is used for randomization.

**Settings and conduct**
This clinical trial study is performed as two Socors in 1399 on leishmaniasis patients who refer to the leishmaniasis clinic of Ghaem Hospital in Mashhad for treatment. All patients receive routine leishmaniasis treatment (glucantime injection). In one group, ciprofloxacin ointment is prescribed, and in the second group, placebo.

**Participants/Inclusion and exclusion criteria**
Inclusion Criteria: Leishmaniasis with direct smear confirmation, clinical course of lesions less than 6 months, no history of leishmaniasis treatment 2 months before entering the study. Exclusion Criteria: age less than 18 years and over 70 years, pregnancy and lactation, use of other therapies during the study period, specific forms of leishmaniasis such as erysipeloid zosteriform and vasospermic and lopoid form

**Intervention groups**
In this study, 52 patients with leishmaniasis were distributed in two groups of 26 patients. Both groups receive routine treatment for leishmaniasis, which involves injecting glucantime. Patients in the first group receive an ointment containing ciprofloxacin to be rubbed twice a day at the site of the leishmaniasis wound during the treatment period. In the second group (control), placebo ointment containing Vaseline is prescribed to be rubbed in the same position and duration.

**Main outcome variables**
improvement, improvement time, size of scare

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20130311012782N46**
Registration date: **2020-05-25, 1399/03/05**
Registration timing: **prospective**

Last update: **2020-05-25, 1399/03/05**
Update count: **0**

**Registration date**
2020-05-25, 1399/03/05

**Registrant information**

**Name**
Ali Mehrabi kushki

**Name of organization / entity**
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-08-21, 1399/05/31

**Expected recruitment end date**
2021-03-17, 1399/12/27

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Study of the additional effect of topical ciprofloxacin on intralesional injection of glucantime in the treatment of cutaneous leismaniasis

**Public title**
effect of adding Cyprofloxacin ointment in treatment of Lishmaniasis

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Having a Lishmaniasi with direct smear confirmation The clinical course of the lesion is less than 6 months No history of leishmaniasis treatment 2 months before entering the study

**Exclusion criteria:**
Pregnancy and lactation Use of other therapies during the study period Specific forms of leishmaniasis, such as erysipeloid, zosteriform, vasoprotective, and lopoid

**Age**
From **18 years** old to **70 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **52**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomization of patients between the two groups is done by Random Allocation Software. In the mentioned software, the volume of the total sample size and the number of groups are entered to the software. The randomization unit in the mentioned software is individual. The software output is a grouped list that randomly distributes the number of samples in two groups. According to the list, patients are distributed in two groups according to the time of referral so that the sample size reaches the required number in each group.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The study is conducted in double blind forms. Patients are unaware of the contents of the topical ointment received. In this way, the medicine is prepared by one of the staff of the clinic who is not in the process of studying in the same packaging and is given to the project executor for prescribing to the patients. Data collection work is also performed by an infectious disease specialist who is unaware of the type of prescription ointment.

**Placebo**
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**
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghaem Street , Mashhad

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
8434193474

**Approval date**
2020-05-18, 1399/02/29

**Ethics committee reference number**
399412

## Health conditions studied

### 1

**Description of health condition studied**
Cutaneous Lishmaniasis

**ICD-10 code**
B55.1

**ICD-10 code description**
Cutaneous leishmaniasis

## Primary outcomes

### 1

**Description**
improvement status

**Timepoint**
Every week for 8 weeks.

**Method of measurement**
Physical examination

### 2

**Description**
improvement time

**Timepoint**
Every week for 8 weeks.

**Method of measurement**
Physical examination

### 3

**Description**
size of scare

**Timepoint**

Ent of treatment

**Method of measurement**

Physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: In this group treated with topical ointment ciprofloxacin liposomes twice a day with a weekly injection of glucocorticoids into the lesion for 8 weeks. Then the size of the lesion (induction) at the time before and 1.5 month after will be evaluated.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: In this group treated with placebo of topical ointment twice a day with a weekly injection of glucocorticoids into the lesion for 8 weeks. Then the size of the lesion (induction) at the time before and 1.5 month after will be evaluated.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Ghaem hospital

**Full name of responsible person**

Mitra Akefi

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Ghaem hospital, Ghaem street, Mashahd, Iran

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

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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**

Javad Yazdanpanah

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Master

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
The plan belongs to the government agency and cannot be published

**Study Protocol**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
No - There is not a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available