

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 leishmaniasis

Protocol summary

Study aim

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

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

Country

Iran (Islamic Republic of)

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+98 31 3629 1510

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mehrabi@mui.ac.ir

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 leishmaniasis

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

Street address

Ghaem hospital, Ghaem street, Mashahd, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ali Mehrabi Koushki

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statistical Consultant

Latest degree

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Other areas of specialty/work

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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