Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparative study of the effect of oral clarithromycin with systemic glucantime on the treatment of acute cutaneous leishmaniasis

Protocol summary

Study aim
Determination of the effect of oral clarithromycin on acute cutaneous leishmaniasis lesions in comparison with systemic glucantime

Design
Patients are divided into intervention and control groups using simple randomization method. Based on first phase of trial, sample size in each group is 20 people. No blinding will be done in this study.

Settings and conduct
This study will be carried out on 20 patients with acute cutaneous leishmaniasis referring to Qaem Hospital and no blinding is done in the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Having an indication of systemic therapy, less than 12 weeks of illness, no previous treatment Exclusion criteria:Pregnancy, breastfeeding, use of other treatment methods during the course of treatment, previous history of local or systemic diseases within less than two months, history of intolerance or allergies tomacrolide, severe underlying diseases, such as heart, kidney and liver diseases

Intervention groups
Intervention group: Qualified patients are treated with oral clarithromycin with 500 mg dosage twice a day for 2 months. Control group: Patients are treated with systemic glucantime with 20 mg/kg dosage for 20 days up to 3 ampoules per day.

Main outcome variables
percentage of complete improvement, size changes, changes in firmness of the lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180411039265N1**
Registration date: **2018-05-05, 1397/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-05, 1397/02/15**
Update count: **0**

Registration date
2018-05-05, 1397/02/15

Registrant information

Name
Naghmeh Zabolinejad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3858 3845

Email address
zabolinejadng@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-11-02, 1395/08/12

Expected recruitment end date
2018-08-21, 1397/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of oral clarithromycin with systemic glucantime on the treatment of acute cutaneous leishmaniasis

Public title
Comparison of the effect of oral clarithromycin with systemic glucantime on the treatment of acute

cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

having an indication of systemic treatment in patients with acute cutaneous leishmaniasis less than 12 weeks of illness receiving no previous treatment

Exclusion criteria:

Pregnancy Breastfeeding Use of other methods of treatment during the course of treatment Past medical history of any local or systemic disease during the last 2 months History of intolerance or allergies to macrolides A significant underlying disease such as heart, renal, or liver diseases. Use of other treatments before referral

Age

From **16 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method is used to divide the patients into intervention and control groups.

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

9177899191

Approval date

2016-10-05, 1395/07/14

Ethics committee reference number

IR.MUMS.fm.REC.1395.289

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

Percentage of complete recovery of the lesion

Timepoint

Follow-up and assessment of recovery are done every two weeks, and the duration of the therapeutic effect of the lesions is assessed based on changes in the size, extent, redness and firmness of the lesions. The treatment period is considered two month. Patients will also be followed 6 weeks, 3 months and 6 months after the treatment is over

Method of measurement

Measuring size of the lesion with digital caliper

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: reception of oral Clarithromycin with 500 mg dosage twice a day for two months

Category

Treatment - Drugs

2

Description

Control group: treatment with systemic glucantime with 20 mg/kg dosage per day for 20 days up to 3 ampules daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Naghmeh Zabolinejad
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Emam Reza Sq, Ebne-sina Ave, Emam Reza hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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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
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Somaye Ghanizadeh
Position
resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is 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

Carrying out analysis on data 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