Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of topical liposomal azithromycin for treatment of acute cutaneous leishmaniasis

Protocol summary

Summary

The aim of this study is evaluation of topical liposomal azithromycin for treatment of acute cutaneous leishmaniasis.Considering inclusion and exclusion criteria, patients will be divided to control and interventional groups and visit every week till 6 weeks for assessing treatment response based on change in induration size (measuring with collis) and erythema. Then improvement response classified to 3 grade a) mild: decrease in induration and erythma < 30% b) moderate:decrease in induration and erythma between 30-60% c)significant: decrease in induration and erythma >60% or getting negative skin smear test

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031216955N1**
Registration date: **2014-05-16, 1393/02/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-16, 1393/02/26

Registrant information

Name
Pouran Layegh
Name of organization / entity
department of dermatology, Ghaem hospital, Mashhad, Iran
Country
Iran (Islamic Republic of)
Phone
+98 51 1801 2861
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momenzadeha1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source
Mashhad University of Medical Sciences

Expected recruitment start date

2009-10-01, 1388/07/09

Expected recruitment end date

2011-10-01, 1390/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of topical liposomal azithromycin for treatment of acute cutaneous leishmaniasis

Public title

Topical treatment of cutaneous leishmaniasis with lipozomal azithromycin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of cutaneous leishmaniasis with less than 12 weeks of clinical course; Not receive any treatment before Exclusion criteria: Pregnancy; Lactating; Receiving simultanous treatment with other methods during treatment course; Sensitivity or intolerance to Macrolids; History of significance renal; Pulmonary and cardiovascular disease

Age

From **1 year** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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
Postal code
Approval date
2008-07-23, 1387/05/02
Ethics committee reference number
2159

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
Lesion improvement
Timepoint
Weekly until 6 weeks
Method of measurement
Measuring the size of induration and ulcer by caliper

Secondary outcomes

1

Description
Side effects
Timepoint
Weekly
Method of measurement
Clinical evaluation

Intervention groups

1

Description
Intervention group: use of topical liposomal Azithromycin twice daily for 6 weeks
Category
Treatment - Drugs

2

Description
Control group: injection of intralesional meglumine antimoniate (glucantime) weekly for 6 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Cutaneous Leishmaniasis Clinic,Ghaem Hospital, Mashhad University of Medical Sciences
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
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
Cutaneous Leishmaniasis Research center, Mashhad University of Medical Sciences

Full name of responsible person
Dr Pouran layegh

Position
Associate professor of dermatology

Other areas of specialty/work

Street address
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Person responsible for scientific inquiries

Contact

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Position
Associate professor of Dermatology

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Akram Momenzadeh

Position
Bachelor of Biology

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