

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

Email address

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 simultaneous 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**

Cutaneous Leishmaniasis Research center, Ghaem
Hospital, Ahmad Abad Street

City

Mashhad

Postal code**Phone**

+98 51 1801 2851

Fax**Email**

layeghpo@mums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**

Cutaneous Leishmaniasis Research center, Ghaem
hospital, Ahmad Abad Street

City

Mashhad

Postal code**Phone**

+98 51 1801 2851

Fax**Email**

layeghpo@mums.ac.ir, src@mums.ac.ir

Web page address**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**Street address**

Cutaneous Leishmaniasis Research Center, Mashhad
University of Medical Sciences

City

Mashhad

Postal code**Phone****Fax****Email**

src@mums.ac.ir

Web page address**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