Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy of Topical Liposomal Azithromycin versus Intralesional Meglumine Antimoniate (Glucantime) in the Treatment of Cutaneous Leishmaniasis

Protocol summary

Summary

This study conducted to compare the therapeutic effects of topical liposomal Azithromycin with interalesional Meglumine Antimoniate (Glucantime) in cutaneous leishmaniasis patients referring to cutaneous leishmaniasis clinic of Ghaem Hospital. In this study 66 patients with approved cutaneous leishmaniasis will enrolled to study. The first group (26 patients) will receive topical liposomal Azithromycin with 40 mg/ml twice daily for 8 weeks. The second group will receive interalesional glucantime weekly that would be infiltrated up to a maximum dose of 2 ml or until it would be paled up to lateral margins of the lesions, for 8 weeks. The results will be evaluated on changes in the size of induration of the lesion weekly. Patient's follow up will be done 6 months and 1 year after treatment. Response rate will determine by measuring the indurations as below: 1. complete improvement (full re-epithelialization of the lesions with or without a negative direct smear result). 2. Significant improvement: decrease in the indurations size >75%. 3. Partial improvement: decrease in the indurations size between 50%-75%. 4. Slight improvement: decrease in the indurations size between 25%-50%. 5. No improvement: decrease in the indurations size<25%.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901312082N2**
Registration date: **2010-04-20, 1389/01/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-04-20, 1389/01/31

Registrant information

Name
Amirali Rahsepar
Name of organization / entity
Mashad University of Medical science
Country
Iran (Islamic Republic of)
Phone
+98 51 1604 2497
Email address
rahseparaa841@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2009-12-24, 1388/10/03

Expected recruitment end date

2012-04-29, 1391/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Topical Liposomal Azithromycin versus Intralesional Meglumine Antimoniate (Glucantime) in the Treatment of Cutaneous Leishmaniasis

Public title

Comparing efficacy of two treatment methods including topical liposomal Azithromycin versus intralesional Meglumine Antimoniate (Glucantime) in the treatment of

cutaneous Leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: cutaneous leishmaniasis with less than 6 months duration approved by either a Giemsa direct skin smear or a positive skin biopsy of lesions, more than 3 month withdrawal from previous history of anti-leishmania therapy. Exclusion criteria: Pregnancy, breast feeding, taking any other specific treatment while participating in the study, past medical history of any systemic disease during the last 2 months, presence of known disease such as cardiac, renal or liver failure.

Age

From **2 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ehtical Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashad University of Medical Sciences

City

Mashhad

Postal code

Approval date

2009-12-22, 1388/10/01

Ethics committee reference number

86724

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

complete healing

Timepoint

Every two weeks up to 8 weeks and then once again after 6 months and 1 year after completing the interventions

Method of measurement

measuring the size of lesion induration diameter with caliper

Secondary outcomes

1

Description

Side effects

Timepoint

Every two weeks till 8 weeks

Method of measurement

Base on taking history and physical examination

Intervention groups

1

Description

Treatment with multilamellar Large Vesicle (MLV) liposomes containing Azithromycin, prepared by freeze drying method, 40 mg/ml twice-daily, according to the lesion's size for 8 weeks or complete healing of the lesion.

Category

Treatment - Drugs

2

Description

Treatment with interalesional meglumine antimoniate (glucantime) injection (1-2 ml) weekly untill 8 weeks or complete healing of the leishmaniasis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Cutaneous Leishmaniasis, Research center for skin disease and cutaneous leishmaniasis

Full name of responsible person
Dr Pouran Layegh, Dr Mohsen Khodami

Street address
Ghaem Hospital, Ahmad Abad Street

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Council of Mashhad University of Medical Sciences

Full name of responsible person
Dr Jalil Tavakoli Afshari

Street address
Central Building of Mashhad University of Medical Sciences

City
Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Council of Mashhad University of Medical Sciences

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
Research center for skin disease and cutaneous leishmaniasis

Full name of responsible person
Hadis Yousefzadeh

Position
Master of sciences

Other areas of specialty/work

Street address
Research center for skin disease and cutaneous leishmaniasis, Ghaem Hospital, Ahmad abad ave

City
Mashhad

Postal code

Phone
+98 51 1841 0135

Fax

Email
hadis_yousefzadeh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Dermatology Department, Ghaem Hospital, 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
Department of Dermatology, Ghaem Hospital, Mashhad University of Medical Sciences

City
Mashhad

Postal code

Phone
+98 51 1881 4988

Fax

Email
layeghpo@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Research center of skin disease and cutaneous leishmaniasis

Full name of responsible person
Hadis Yousefzadeh

Position
Master of Sciences

Other areas of specialty/work

Street address

City
Mashhad

Postal code

Phone

Fax

Email
hadis_yousefzadeh@yahoo.com

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