

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of topical liposomal azithromycin plus azithromycin and azithromycin in the treatment of cutaneous leishmaniasis.

Protocol summary

Study aim

Comparison of topical liposomal azithromycin plus azithromycin and azithromycin in the treatment of cutaneous leishmaniasis.

Design

Clinical trials with control group, with parallel groups, blind, randomized

Settings and conduct

Patients referred to the dermatologic and infectious clinics and the Clinic of the Dermatology Center of Isfahan Dermatology Research Center, who had the inclusion criteria mentioned, entered the study. Patient information was obtained through a questionnaire, clinical examination and photographic examination and was recorded in a checklist. The information includes the number of lesions, the size of the lesions, the location of the lesions, the patient's age, the history of the disease and the complications of azithromycin. Patients are randomly assigned into two intervention and control groups. Patients and data analyst are unaware of the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: new cases of cutaneous leishmaniasis; 1-5 lesions with 3 cm and diameter more than 3 cm.

Non-Inclusion criteria: more than 5 lesions; lesions on face, neck, joint and mucosal sites or sporotrichoid like lesions; lung surface size is more than 5 Square centimeters; the patient is pregnant or breastfeeding.

Intervention groups

The intervention group included 20 oral and topical azithromycin (lesion) samples and control group with 20 oral and placebo-receiving azithromycin recipients

Main outcome variables

Lung size; complications of azithromycin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180425039414N1**

Registration date: **2019-07-27, 1398/05/05**

Registration timing: **retrospective**

Last update: **2019-07-27, 1398/05/05**

Update count: **0**

Registration date

2019-07-27, 1398/05/05

Registrant information

Name

Atousa Hakamifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 5555

Email address

a.hakamifard@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-03-20, 1397/12/29

Scientific title

Comparison of topical liposomal azithromycin plus azithromycin and azithromycin in the treatment of cutaneous leishmaniasis.

Public title

Liposomal azithromycin in cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

New cases of cutaneous leishmaniasis 1-5 lesions with 3 cm and diameter more than 3 cm

Exclusion criteria:

More than 5 lesions Lesions on face, neck, joint and mucosal sites or sporotrichoid like lesions Lung surface size is more than 5 Square centimeters The patient is pregnant or breastfeeding.

Age

From **1 year** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

The number of lesion in patients was 2 on average. But some patients also had a lesion. In general, any disease with less than 5 lesions according to the conditions of entry into the sample was included in the study and each lesion was considered as a separate sample.

Actual sample size reached: **15**

More than 1 sample in each individual

Actual sample size in each individual: **2**

The number of lesion in patients was 2 on average. But some patients also had a lesion. In general, any disease with less than 5 lesions according to the conditions of entry into the sample was included in the study and each lesion was considered as a separate sample.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into two intervention groups (receiving oral and topical azithromycin) and control (oral azithromycin and placebo recipients) using spss computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in both groups received oral azithromycin therapy and randomly received a placebo group and the other group receiving topical intervention, and patients were unaware of the treatment content. Information is provided to the data analyst after being ignored and tagged.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Soffeh Ave

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2018-09-02, 1397/06/11

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.144

Health conditions studied

1

Description of health condition studied

Leishmaniasis

ICD-10 code

Infections

ICD-10 code description

L00-L08

Primary outcomes

1

Description

Leishmaniasis

Timepoint

6 weeks, 12 weeks and 6 months after treatment

Method of measurement

Digital photography

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: Local topical liposomal erythromycin, which was coated every 12 hours on the surface of the surface, with an oral erythromycin capsule of 500 mg every 12 hours

Category

Treatment - Drugs

2

Description

Control group: Localized liposomal erythromycin, which was applied every 12 hours on the surface of the site, plus a daily 5 cc placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Leishmaniasis Research Center

Full name of responsible person

Atousa Hakamifard

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Soffeh Ave, Alzahra Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

Hezarjerib Ave, Isfahan University Of Medical Sciences

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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

Esfahan University of Medical Sciences

Proportion provided by this source

50

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

Esfahan University of Medical Sciences

Full name of responsible person

Atousa Hakamifard

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

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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 information is non-identifiable and can be shared after two years after printing.

When the data will become available and for how long

Two years after the publication of the article

To whom data/document is available

Physicians, assistants and specialists in the field of skin

Under which criteria data/document could be used

To compare the present information with the following information or with other therapeutic procedures

From where data/document is obtainable

Send an e-mail to a.hakamifard@med.mui.ac.ir and get permission from the research deputy of Isfahan University of Medical Sciences.

What processes are involved for a request to access data/document

Send an e-mail to a.hakamifard@med.mui.ac.ir and get permission from the research deputy of Isfahan University of Medical Sciences.

Comments