

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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

#### Street address

Soffeh Ave, Alzahra Hospital

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174675731

#### Phone

+98 31 3668 5555

#### Email

a.hakamifard@med.mui.ac.ir

## 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

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3668 0042

#### Email

a.hakamifard@med.mui.ac.ir

### 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

### Contact

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Esfahan University of Medical Sciences

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Esfahan University of Medical Sciences

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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**