

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing evaluation of oral Azithromycin and cryotherapy in cutaneous leishmaniasis in children

#### Protocol summary

##### Summary

The aim of this study is comparing efficacy of two treatment methods including oral azithromycin and cryotherapy in children with cutaneous leishmaniasis caused by leishmania tropica. Sixty six patients below 14 years old (two groups with 33 individuals) that their cutaneous leishmaniasis have been diagnosed by direct skin smear (Giemsa staining method) or skin biopsy and their clinical lesion have longed less than 6 months will enter to study. The first group will be treated with oral azithromycin 10-12mg/kg daily up to 10 days in first session and then it will be repeated during 3 following periods. The second group will be treated with cryotherapy 10-20 s weekly, until the lesion with 1 mm of its surrounding are completely infiltrated. The result will be recorded as changes of lesion indurations basis in each follow up visit. Patients will be followed for 3 months after finishing treatment and lesion indurations and possible side effects will be recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903023862N3**

Registration date: **2010-05-23, 1389/03/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-05-23, 1389/03/02

##### Registrant information

##### Name

Farahzad Jababri Azad

##### Name of organization / entity

Mashahd University of Medical Scineces

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1843 6626

##### Email address

banihashemim@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Council of Mashhad University of Medical Sciences

##### Expected recruitment start date

2007-08-21, 1386/05/30

##### Expected recruitment end date

2010-07-21, 1389/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing evaluation of oral Azithromycin and cryotherapy in cutaneous leishmaniasis in children

##### Public title

Comparing two methods of oral Azithromycin and cryotherapy in cutaneous leishmaniasis treatment in children

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: presence of cutaneous leishmaniasis with less than 6 months of clinical course that their disease have been approved by direct smear and stained with giemsa method or skin biopsy, age<14, a 3-month treatment free interval from the last treatment course. Exclusion criteria: pregnancy, lactating, receiving simultaneously any therapy that has antileishmaniasis

effect during 2 months ago, history of significance renal, pulmonary and cardiovascular disease, sensitive to azithromycin.

#### **Age**

From **1 year** old to **14 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**

Ethics Committee of Mashhad University of Medical Sciences

###### **Street address**

Central Building of Mashhad University of Medical Sciences

###### **City**

Mashhad

###### **Postal code**

##### **Approval date**

2007-06-10, 1386/03/20

##### **Ethics committee reference number**

6250

### **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**

For the first intervention, at the end of each month until 4 months and for second intervention at the end of 8th week and during follow up of patients in both studied group after 3 months of beginning of the study

##### **Method of measurement**

Measuring the size of induration and ulcer

### **Secondary outcomes**

#### **1**

##### **Description**

Side effects

##### **Timepoint**

At each follow up visit

##### **Method of measurement**

physical exam

### **Intervention groups**

#### **1**

##### **Description**

Treatment with oral azithromycin 10-12 mg/kg daily until 10 days and then repeat during 3 consecutive periods according to the improvement basis

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Treatment with cryotherapy 10-20 s, until the lesion with 1 mm of its surrounding become fully infiltrated, weekly up to 8 weeks based on lesion size or complete lesion improvement

##### **Category**

Treatment - Other

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Research Center of Skin Disease and Cutaneous leishmaniasis, Ghaem Hospital

###### **Full name of responsible person**

Dr Mahnaz Banihashemi, Dr Shagufta Nargis

###### **Street address**

###### **City**

Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research Council of Mashhad University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research of Mashhad University of Medical Sciences

**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, Biologist

**Other areas of specialty/work****Street address**

Research center of skin diseases and cutaneous leishmaniasis, Ghaem Hospital

**City**

Mashhad

**Postal code****Phone**

+98 51 1841 0135

**Fax****Email**

src@mums.ac.ir , hadis\_yousefzadeh@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Department of Dermatology, Ghaem Hospital, Mashad University of Medical Sciences

**Full name of responsible person**

Dr Mahnaz Banihashemi

**Position**

Associate Professor of Dermatology

**Other areas of specialty/work****Street address**

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**City**

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**Postal code****Phone**

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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*