Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

Phone

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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 Mashad 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 untill 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 Mashad 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 Scinences, Biologist

Other areas of specialty/work

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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

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Other areas of specialty/work

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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