

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of Clofazimine Effect in Treatment of Cutaneous Leishmaniasis

Protocol summary

Summary

We studied effect of Clofazimine on cutaneous leishmaniasis to find new and easier way in treatment of the disease. Twenty four patients was selected from patients that referred to Shahid-Faghihi Hospital during 22 September 2007 to 5 December 2008. Patients received Clofazimine 50 -100 mg/day according to weight of patient for 3 weeks. Inclusion criteria: age more than 12 y/o, duration of disease less than 2month, no anti-leishmanial treatment(Glucantim, Rifampin, Azithromycin) since 1month prior to study, Exclusion criteria: pregnancy, lactation, severe diseases including; hepatic, respiratory and renal disease. Lesion of patients scored according to size, indurations, erythema and ulceration at the baseline, end of treatment period and end of the study (weeks 0, 3, and 6 respectively). We considered one point of score for 5mm of each of these indices and defined as a number. The sum of these numbers was considered as patient's score. Treatment was defined as complete re-epithelialization of lesion, partial treatment as more than 60% improvement in the score of lesions and failure of treatment was considered as improvement of score equal or less than 60%.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710251543N1**

Registration date: **2009-05-08, 1388/02/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-05-08, 1388/02/18

Registrant information

Name

jaber mazandarani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1231 9049

Email address

jmaz@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Fars University of Medical Sciences and Health services

Expected recruitment start date

2007-09-22, 1386/06/31

Expected recruitment end date

2008-12-05, 1387/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Clofazimine Effect in Treatment of Cutaneous Leishmaniasis

Public title

Clofazimine Effect on Cutaneous Leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 12 y/o, duration of disease less than 2month, no anti-leishmania (Glucantim, Rifampin, Azithromycin) treatment since 1 month prior to study, Exclusion criteria: Lesion on face and joint, pregnancy, lactation, severe diseases including hepatic, renal and cardiac diseases

Age

From **12 years** old to **139 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Fars University of Medical Sciences and Health Services

Street address

Karim khan zand street

City

Shiraz

Postal code

713484419

Approval date

2007-06-28, 1386/04/07

Ethics committee reference number

2551

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 with re-epithelialization of cutaneous lesion

Timepoint

3 week

Method of measurement

Physical examination and change of score, including: erythema, induration, ulceration and size of lesions

Secondary outcomes

1

Description

Adverse effect

Timepoint

3 weeks

Method of measurement

Physical examination and medical history

Intervention groups

1

Description

Clofazimine capsule,50-100mg/day ,orally for 3 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Department, Shahid-Faghihi Hospital

Full name of responsible person

Dr.Mohammad Reza Namazi

Street address

Dermatology Department, Shahid-Faghihi Hospital, Karimkhan zand street

City

Shriaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fars University of Medical Sciences and Health Services

Full name of responsible person

Dr.Dabbaghmanesh, Vice chancellor for research

Street address

Karimkhan zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Fars University of Medical Sciences and Health Services

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**

Fars University of Medical sciences and Health Services

Full name of responsible person

Dr. Jaber Mazandarani

Position

Dermatology resident

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Fars University of Medical Sciences and Health Services

Full name of responsible person

Dr. Jaber Mazandarani

Position

Dermatology resident

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

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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***Person responsible for scientific inquiries****Contact****Name of organization / entity**

Fars University of Medical Sciences and Health Services

Full name of responsible person

Dr. Mohammad Reza Namazi

Position

Assistant Professor

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

Karmkhan zand st. Shahid Faghihi Hosp. Dermatology