Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Scienses

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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
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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
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
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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