Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of two regimens of fluconazol 200 mg and 400 mg daily in the treatment of cutaneous lieshmaniasis

Protocol summary

Summary

Cutaneous leishmaniasis is one of difficulties in our country and different treatments have been used for it. Each of these treatments has its own benefits and dangers. The goal of this study is to prove better efficacy of fluconazol 400mg daily rather than 200mg daily for the treatment of cutaneous leishmaniasis. According to the statistical calculations, sample size of our study is 94 cases. These patients will be selected from patients who refer to Shiraz Faghihi hospital for treatment. Inclusion criteria: age over 12 years; positive PCR for leishmanisis and no treatment during two months ago; duration of disease lower than 4 months. Exclusion criteria: pregnancy; breast feeding; possibility of pregnancy in future; number of lesion over ten; history of liver disease and high BUN or Cr. Patients will be divided into two groups. The patients who set in odd numbers take oral fluconazol 200mg/daily and the patients who set in even numbers take oral fluconazol 400mg/daily. Then response to the treatment defines by decrease or elimination of induration and size of the lesions and re-epithelialization . The patients follow every two week for six weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710221542N1**
Registration date: **2009-05-18, 1388/02/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-05-18, 1388/02/28

Registrant information

Name

Fariborz Hayati

Name of organization / entity

Shiraz University of Medical Scienses

Country

Iran (Islamic Republic of)

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+98 71 1227 6809

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fhayati@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of medical scienses

Expected recruitment start date

2007-12-21, 1386/09/30

Expected recruitment end date

2009-02-19, 1387/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two regimens of fluconazol 200 mg and 400 mg daily in the treatment of cutaneous lieshmaniasis

Public title

Comparison of two regimens of fluconazol in treatment of cutaneous lieshmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age over 12 years, positive PCR for leishmanisis and no treatment in two months ago, duration of disease is lower than 4 months. Exclusion criteria: pregnancy, breast feeding, possibility of

pregnancy in future, number of lesion over ten, history of liver disease and high BUN or Cr.

Age
From **12 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **94**

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

1

Registry name

Secondary trial Id

Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Scienses

Street address
Zand Karim khan Bolvar

City
Shiraz

Postal code
7134844119

Approval date
2008-12-05, 1387/09/15

Ethics committee reference number
ct-87-3996

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
reepithelialization

Timepoint
every two week

Method of measurement
observation

2

Description
size of lesion

Timepoint
every two week

Method of measurement
with ruler

3

Description
Induration of lesion

Timepoint
every two week

Method of measurement
physical examination

Secondary outcomes

1

Description
Rising of liver enzyme, BUN and Cr

Timepoint
every two week

Method of measurement
Blood sample and laboratory measurment

2

Description
Nausea and vomitting

Timepoint
every two week

Method of measurement
History

Intervention groups

1

Description
First group: fluconazol 200mg/daily for six weeks

Category
Treatment - Drugs

2

Description
Second group: fluconazol 400mg/daily for six weeks

Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Faghihi Hospital
Full name of responsible person
Hayati Fariborz
Street address
Faghihi Hospital- Zand Karimkhan Bolvar
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Scienses
Full name of responsible person
Dabaghmanesh mohammad hosain MD
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Zand Karimkahn Bolvar - Shiraz University of Medical Scienses
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Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Scienses
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
Shiraz University of Medical Sciences
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Hayati Fariborz MD
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Person responsible for scientific inquiries

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Hayati Fariborz MD
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resident of dermatology
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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