

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 leishmaniasis

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 leishmaniasis 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 Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1227 6809

Email address

fhayati@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of medical sciences

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 leishmaniasis

Public title

Comparison of two regimens of fluconazol in treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age over 12 years, positive PCR for leishmaniasis 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 Sciences

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 measurement

2

Description

Nausea and vomiting

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 Sciences

Full name of responsible person

Dabaghmanesh mohammad hosain MD

Street address

Zand Karimkahn Bolvar - Shiraz University of Medical Sciences

City

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 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

Shiraz University of Medical Sciences

Full name of responsible person

Hayati Fariborz MD

Position

Resident of Dermatology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr.Maryam Emad

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Assistant Professor

Other areas of specialty/work

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Full name of responsible person

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resident of dermatology

Other areas of specialty/work

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Email

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