Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Efficacy of combination therapy with oral fluconazole and topical cryotherapy on cutaneous leishmaniasis lesions in comparison to topical cryotherapy alone

Protocol summary

Summary

In the present study combination treatment with oral fluconazole and cryotherapy is compared to cryotherapy alone to evaluate for any increased efficacy. New cases of smear positive cutaneous leishmaniasis with negative past history of leishmaniais sequentially enroll in the groups of the study at the time of presentation for treatment while those with pregnancy or lactation, location on the face and ear or more than 10 lesions are excluded. The study is designed as a randomized double blind clinical trial with required number of 30 participant in each group of cases and controls.To blind for the patient and assessors the drug and placebo were packed identically in the pharmacy as 50 mg capsules so that the only difference is the assigned letter A or B. Statistical analyst is also blinded. Allocation to groups achieved according to randomized block design (AB and BA). Duration of drug treatment is 6 weeks but cryotherapy continues till complete re-epithelialization. Each enrolling patient (case or control) is examined and required parameters of the lesions including the diameter,degree of induration and area of ulcer are registered at the beginning of the treatment and weekly. Evaluation for primary outcome (final recovery) is done at the end of 6th week when another smear of leishmania is done and 4 weeks later. Definition for outcome is as follows: Complete recovery equals to absence of induration and complete re-epithelialization during the treatment period and the following 4 weeks; No recovery is defined as positive smear or less than 50% reduction in induration and partial recovery means negative smear and more than 50% reduction in induration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112320052N1**
Registration date: **2015-10-27, 1394/08/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-27, 1394/08/05

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research of Fasa University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of combination therapy with oral fluconazole and topical cryotherapy on cutaneous leishmaniasis lesions in comparison to topical cryotherapy alone

Public title
The effect of combination therapy with oral fluconazole and topical cryotherapy on cutaneous leishmaniasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: New case of smear positive cutaneous leishmaniasis; Negative past history of leishmaniais; Weight above 10 kilogram; No treatment for leishmaniasis during the previous 3 months; Disease duration of less than 3 months. Exclusion criteria: Pregnancy and lactation; Skin lesions located on face and ear; More than 10 skin lesions; Present or past history of renal or cardiac diseases; Lupoid or sporotrichoid leishmaniasis; Clients with Immunedeficiency, HIV or Diabetes
Age
From **5 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Fasa University of Medical Sciences
Street address
Fasa University of Medical Sciences, Ebn-Sina Square
City
Fasa
Postal code
Approval date
2015-05-05, 1394/02/15
Ethics committee reference number
IR.FUMS.REC.13.94

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
Recovery rate
Timepoint
6 weeks (at the end of drug therapy) and 10 weeks after the start of trial
Method of measurement
Degree of induration, Smear positivity, Ulcer area

Secondary outcomes

1

Description
Leishmania Smear
Timepoint
at the begining and the end of 6th week of treatment
Method of measurement
Laboratory report

2

Description
Induration Severity
Timepoint
Weekly till 6th week and 4 weeks later
Method of measurement
palpation and measuring diameter and height of induration

3

Description
Area of ulceration
Timepoint
Weekly till 6th week and 4 weeks later
Method of measurement
observation measuring in centimetr square

4

Description
Lesion diameter
Timepoint
Weekly till 6th week and 4 weeks later
Method of measurement

observation measured in centimeter by ruler

5

Description
Type of cutaneous Leishmania
Timepoint
at the begining of the trial
Method of measurement
observation

6

Description
Number of skin lesions
Timepoint
at the start of the trial
Method of measurement
observation

7

Description
Time elapsed to present since the begining of the lesion
Timepoint
at the start of the trial
Method of measurement
Asking the participant

8

Description
Adverse events
Timepoint
Weekly till 6th week and 4 weeks later
Method of measurement
Asking the participant and examination

Intervention groups

1

Description
Intervention: Fluconazole 1 cap 50 mg for each 8kg body weight daily (maximum 400mg) for 6 weeks + Cryotherapy weekly till complete recovery
Category
Treatment - Drugs

2

Description
Control: placebo1 cap 50 mg for each 8kg body weight daily (maximum 400mg) for 6 weeks + Cryotherapy weekly till complete recovery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh OPD Clinic
Full name of responsible person
Dr Ahmad Reza Parhizkar
Street address
Parastar Boulvard
City
Fasa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Fasa University of Medical Sciences
Full name of responsible person
Dr Ehsan BahramAli
Street address
Fasa University of Medical Sciences, Ebn-Sina Square
City
Fasa
Grant name
Grant code / Reference number
93143
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Fasa 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
Fasa Univaersity of Medical Sciences
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Dr Ahmad Reza Parhizkar
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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