

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 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 leishmaniasis 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

Name

Ahmad Reza Parhizkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5331 6300

Email address

parhizkara@sums.ac.ir

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

IR.FUMS.REC.13.94

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 leishmaniasis; 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 Immunodeficiency, 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

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 beginning 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 beginning 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 beginning 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: placebo 1 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 Boulevard

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

Full name of responsible person

Dr Ahmad Reza Parhizkar

Position

Clinical Dermatologist

Other areas of specialty/work

Street address

Vali-Asr Hospital, Ebn-Sina Square

City

Fasa

Postal code

Phone

+98 71 5331 5012

Fax**Email**

ahmadrparhizkar@yahoo.com; parhizkara@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Fasa University of Medical Sciences

Full name of responsible person

Dr. Ahmad Reza Parhizkar

Position

Clinical Dermatologist

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

Vali-Asr Hospital, Ebn-Sina Square

City

Fasa

Postal code**Phone**

+98 71 5331 5012

Fax**Email**

ahmadrparhizkar@yahoo.com; parhizkara@sums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Fasa University of Medical Sciences

Full name of responsible person

Dr. Ahmad Reza Parhizkar

Position

Clinical Dermatologist

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

Vali-Asr Hospital, Ebn-Sina Square

City

Fasa

Postal code**Phone**

+98 71 5331 5012

Fax**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