

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of oral miltefosin on treatment of chronic anthropological cutaneous leishmaniasis

Protocol summary

Study aim

Treatment of antroponotic cutaneous leishmaniasis resistant classes with oral miltefosine

Design

Randomized Controlled Trial

Settings and conduct

Patient who do not respond glugantim treatment at Ghaeme Hospital in Mashhad will first be asked for a polymerase chain reaction (PCR) test and after the tests confirmation, the initial test for liver and kidney and cell blood count (CBC) would be asked and if they were normal, we will start a 28-day oral miltefosine course (by weight)

Participants/Inclusion and exclusion criteria

Entrance Standard: People over two years old;. Exit Standard: 1- Pragnansy 2- Lactation 3- Renal, Kidny and Heart Disorder 4- Cytopenia

Intervention groups

Patients with leishmaniasis who were resistance with two courses of systemic glocantim therapy was threaded by a 28-day course of oral multifocin

Main outcome variables

Indoration Change , Side effect of treatment , Control of urea creatinine tests ,Liver enzyme, Blood cell count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200302046673N1**

Registration date: **2020-05-10, 1399/02/21**

Registration timing: **retrospective**

Last update: **2020-05-10, 1399/02/21**

Update count: **0**

Registration date

2020-05-10, 1399/02/21

Registrant information

Name

Masoume Tayebi

Name of organization / entity

Country

United States of America

Phone

+1 513-867-5473

Email address

tayyebims961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-10-26, 1398/08/04

Trial completion date

2020-10-25, 1399/08/04

Scientific title

Effect of oral miltefosin on treatment of chronic anthropological cutaneous leishmaniasis

Public title

The effect of oral miltefosin on treatment resistant cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with antroponotic leishmaniasis over two year who have not received remission despite two courses of systemic glucontime or one cours of systemic glugantime plus one course of intraleasional injection

Exclusion criteria:

Children Under Two Year Pregnancy and Lactation Renal Disorder Liver Disorder Heart Disease Cytopenia

Age
From **2 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **27**
Actual sample size reached: **27**

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Fakuri Boulevard 8, Villa 9, No. 2

City

Mashhad

Province

Razavi Khorasan

Postal code

91179104014

Approval date

2018-11-20, 1397/08/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.604

Health conditions studied

1

Description of health condition studied

Cutaneous Leishmaniasis Antroponotic

ICD-10 code

B55.1

ICD-10 code description

Cutaneous Leishmaniasis

Primary outcomes

1

Description

Endoration Rate of Leasion

Timepoint

Study days 0,14,28,90,180,360

Method of measurement

Ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Miltefosin made in PROFONDA Co.in India 50 mg. 2.5mg/kg/day for 28 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Vahid Mashayekhi Ghoyonlo

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vakilabad Highway - Azadi Square - University

Campus - Medical School

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Razavi Khorasan
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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
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

2

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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100
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Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty

Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoume Tayebi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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Full name of responsible person

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Latest degree

Medical doctor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable