Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of topical thermotherapy (with thermomed) in the treatment of anthroponotic Leishmaniasis in a pilot study

Protocol summary

Summary

Objective:The aim of this phase 3,clinical study is to evaluate the effect of topical thermotherapy (with thermomed) in the treatment of anthroponotic Leishmaniasis. Design: In leishmaniasis clinic of Imam Reza hospital, twenty cases of Cutaneous Leishmaniasis will be selected accidentaly. Inclusion criteria are: confirmed diagnosis of cutaneous Leishmaniasis by PCR lesions, less than six months of duration, informed consent for participation. Exclusion Criteria are; pregnancy, more than 5 lesions, Very extensive lesions (more than ten centimeters). Setting: The lesion will be treated with thermotherapy (50 degree of Centigrade for 30 seconds) one cession and after one month, patients will be visited and the lesion changes and probable side effects would be recorded. For cases in which the considerable induration in lesions remains, treatment will be carried out once again. After 6 months of treatment, patients will be visited again and evaluated and the course of disease and possible complications would be recorded. main outcome measures: Finally, the patients will be divided into three categories in terms of lesion consistency and size (the size of induration). Early improvement: more than 50% of reduced induration during three months after treatment. Definite improvement: including early improvement and not return of lesion during in the six-month follow-up. Failure of treatment: increased the lesion size or improvement of less than 50% of lesions in 3 months follow up or return of the lesion in six months follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011816554N2**
Registration date: **2016-01-03, 1394/10/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-01-03, 1394/10/13

Registrant information

Name

Vahid Mashayekhi-Goyonlo

Name of organization / entity

Mashhad University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical thermotherapy (with thermomed) in the treatment of anthroponotic Leishmaniasis in a pilot study

Public title

Evaluation of the effect of topical thermotherapy (with thermomed) in the treatment of anthroponotic

Leishmaniasis in a pilot study

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: clinical features of lesion consistent with Anthroponrtic leishmaniasis; specified L. tropica with Molecular method PCR; the patient has indication for local therapy based on clinical judgment; up to 6 months of the lesion duration; the patient already not had any treatment for cutaneous Leishmaniasis; consent for participate in this study. Exclusion Criteria: incompetence for regular follow-up; presence of secondary infection of the lesions based on clinical features and physician judgment; Use of other treatments during the study; Very extensive lesions (more than ten centimeters); presence of necrosis and the lesions deeper than hypodermis; Lesions on the face and joints; having a pacemaker and prosthetic; pregnancies.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

Central building of Mashhad University of Medical Sciences(Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Postal code

Approval date

2015-01-21, 1393/11/01

Ethics committee reference number

930460

Health conditions studied

1

Description of health condition studied

Anthroponotic Leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Lesion healing

Timepoint

Three monthly

Method of measurement

Measuring the size of induration and formidability

Secondary outcomes

1

Description

Side effects

Timepoint

Three monthly

Method of measurement

Efficacy and side effects including local and systemic reactions will be recorded according to patient's report and clinician observation

Intervention groups

1

Description

Thermotherapy: one time (30 seconds at 50 ° C)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Research center for skin disease and cutaneous leishmaniasis

Full name of responsible person

Dr Vahid mMashayekhi

Street address

Department of dermatology, Imam Reza hospital, Ebn Sina Ave.

City

Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Mashhad 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
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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