

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluating the Efficacy of thermotherapy in treatment of patients with cutaneous leishmaniasis

Protocol summary

Summary

The aim of this study is to evaluate the therapeutic effects of diathermy (thermotherapy) on skin lesions of cutaneous leishmaniasis. Thirty five cases of cutaneous leishmaniasis with less than six months of duration, diagnosed by direct positive smear, would be enrolled to study. The therapeutic intervention is thermotherapy by microwave and short wave infra-red; 3 sessions per week until 4-6 weeks (each session include 45 0C for 10 minutes). Lesion size changes will be recorded during treatment period and finally the results will be classified as complete improvement (90-100%), good improvement (70-90%), moderate improvement (50-70%) and no response (below 50%). Also the patients will be visited 6 weeks after the last therapeutic intervention to assess the lesion status and likely side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903183862N5**

Registration date: **2010-06-08, 1389/03/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-06-08, 1389/03/18

Registrant information

Name

Farahzad Jababri Azad

Name of organization / entity

Mashahd University of Medical Scineces

Country

Iran (Islamic Republic of)

Phone

+98 51 1843 6626

Email address

banihashemim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2007-10-16, 1386/07/24

Expected recruitment end date

2010-08-18, 1389/05/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Efficacy of thermotherapy in treatment of patients with cutaneous leishmaniasis

Public title

Evaluating the effects of thermotherapy on cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: confirmed cutaneous leishmaniasis by direct smear, less than 6 months of clinical duration, ulcer size less than 1 cm that limits topical application thermotherapy, signing of inform consent form for using this treatment modalities. Exclusion criteria: presence of lesion in sensitive sites to thermotherapy, patients who under simultaneous treatment for cutaneous leishmaniasis.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 35

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 Mashad University of Medical Sciences

Street address

Central Building of Mashad University of Medical Sciences, Mashad,

City

Mashhad

Postal code

Approval date

2007-04-08, 1386/01/19

Ethics committee reference number

6209

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

lesion healing

Timepoint

weekly

Method of measurement

measuring the size of induration and ulcer by caliper

Secondary outcomes

1

Description

side effect

Timepoint

weekly

Method of measurement

clinical evaluation

Intervention groups

1

Description

Thermotherapy: 4 to 6 weeks (3 times weekly - ten minutes each time)

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 Mashayekhi

Street address

Dermatology Department, Imam Reza Hospital, Avicennia street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Mashhad University of Medical Sciences

Full name of responsible person

Vice chancellor for Research

Street address

Central Building of Mashhad University of Medical Sciences

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Council 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

Research center for skin disease and cutaneous leishmaniasis

Full name of responsible person

Hadis Yousefzadeh

Position

Master of Sciences, Biologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Dermatology, Imam Reza Hospital, Mashad University of Medical Sciences

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Person responsible for updating data

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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