

# 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**

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**Name of organization / entity**

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

**Full name of responsible person**

Dr Vahid Mashayekhi Ghoyonlo

**Position**

Assistant professor of Dermatology

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Research center for skin disease and cutaneous leishmaniasis, Ghaem Hospital, Mashhad Medical Univers

**Full name of responsible person**

Hadis Yousefzadeh

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**Postal code**

**Phone**

**Fax**

**Email**

hadis\_yousefzadeh@yahoo.com

**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*