Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 diseae 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 Mashad 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 Scinences, Biologist

Other areas of specialty/work

Street address
Research center of skin diseases and leishmaniasis, Office building, Ahmad Abad Street, Ghaem Hospital

City
Mashhad

Postal code

Phone
+98 51 1841 0135

Fax

Email
hadis_yousefzadeh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

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

Other areas of specialty/work

Street address
Department of Dermatology, Imam Reza Hospital, Avicenna Street, Imam Reza square

City
Mashhad

Postal code

Phone
+98 51 1802 2490

Fax

Email
mashayekhiv@mums.ac.ir , vahid4706@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Research center for skin disease and cutaneous leihmaniasis, Ghaem Hospital, Mashhad Medical Univers

Full name of responsible person
Hadis Yousefzadeh

Position
Master of Sciences, Biologist

Other areas of specialty/work

Street address
research center of skin diseases and leishmaniasis, Office building, Ahmad Abad Street, Ghaem Hospital

City
Mashhad

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