

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of Microwave Thermotherapy versus Intralesional Antimonial in Treatment of Cutaneous Leishmaniasis

#### Protocol summary

##### Study aim

Determination of the Effectiveness of Local Thermotherapy by Microwave Method Compared to Intralesional Injection in Patients with Cutaneous Leishmaniasis

##### Design

In the intervention group, Microwave Thermotherapy was performed for 15 minutes with a distance of 2 cm from the outlet wound 60 watts twice a week to 12 sessions. In the control group, intra-lesional antimonial was injected as prescribed by the National Committee for leishmaniasis (8-12 sessions). Simple randomization. sample size is the pilot .

##### Settings and conduct

In this study, patients who come to Imam Reza Hospital and Ghaem Hospital and the Center for Health ab va bargh in 1397-98, are admitted to the study by maintaining entry and exit criteria and obtaining informed consent.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: Diagnosis by smear or biopsy of skin lesions has been approved, failure to receive an effective medication in the treatment of leishmaniasis in a month ago, patient's informed consent, and the signing of written consent.

##### Intervention groups

In the intervention group, microwave therapy was performed for 15 minutes at intervals of 2 cm with 60 watts twice a week, up to 12 sessions.

##### Main outcome variables

The induration and size of the lesion before and after the treatment, as well as 3 months and 6 months and one year after treatment, the percentage of patients / lesions improved at the end of the third month, the rate of improvement, the severity of the pain in each group, the severity of the pain in each group, Scare rate in the last review.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181012041313N1**

Registration date: **2019-04-03, 1398/01/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-03, 1398/01/14**

Update count: **0**

##### Registration date

2019-04-03, 1398/01/14

##### Registrant information

##### Name

Naeime Ebrahimabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3509 8109

##### Email address

ebrahimabadi961@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-23, 1397/12/04

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Microwave Thermo-therapy versus Intralesional Antimonial in Treatment of Cutaneous Leishmaniasis

#### Public title

Evaluation of Microwave Thermo-therapy versus Intralesional Antimonial in Treatment of Cutaneous Leishmaniasis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Diagnosis by smear or biopsy of skin lesions is confirmed lack of effective medication in the treatment of leishmaniasis in a month ago patient's informed consent the signing of written consent.

##### Exclusion criteria:

Infectious or ulcerative lesions, inappropriate patient cooperation patient's desire to withdraw from study. pregnancy and lactation. secondary infection based on clinical presentation lesions near eye nerves and Testis having a pacemaker and prosthesis at the treatment site very extensive lesions (more than 10 centimeters) patients with sporotrichoid lesions chronic diseases such as diabetes mellitus and peripheral neuropathy

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Outcome assessor

#### Sample size

Target sample size: **20**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple. This method use simple randomization models such as tossup, the use of a random number table, or the use of computer randomization methods. And any one who refers, puts in the intervention or control group, for example, dropping a coin, flip. The implementation of this method is very simple. The disadvantages of this method are that the sample size of a group may be more than the other. One type of intervention may be given early in the study and a type of intervention late in the study. Between patients who have entry and exit conditions draw and randomly select individuals and we add the intervention and control group.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Assessors and analysts are unaware of the intervention and control groups.

#### Placebo

Not used

#### Assignment

Parallel

#### 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

Vakil Abad Highway-Azadi Square-Pardis University-Faculty of Medicine

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

#### Approval date

2019-02-23, 1397/12/04

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.707

## Health conditions studied

### 1

#### Description of health condition studied

leishmaniasis

#### ICD-10 code

B55.1

#### ICD-10 code description

Cutaneous leishmaniasis

## Primary outcomes

### 1

#### Description

Induration of lesion

#### Timepoint

Before and after treatment, as well as 3 months and 6 months and one year after treatment

#### Method of measurement

ruler

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Microwave Thermo-therapy for 15 minutes with a distance of 2 centimeters from the wound site at 60 watts twice a week, up to 12 sessions.

#### Category

Treatment - Devices

**2**

**Description**

Control group: In the control group, intra-lung antimycelial injection was performed according to the instructions of the State Committee for Sickle (8-12 sessions).

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Clinic of Imam Reza and Ghaem Hospital and Ab V Bargh Center

**Full name of responsible person**

Masoud Maleki

**Street address**

Shariati Square, Imam Reza Hospital (AS)

**City**

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Razavi Khorasan

**Postal code**

9137913316

**Phone**

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**Email**

MalekiM@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Vakil Abad Highway-Azadi Square-Pardis University-Faculty of Medicine

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**Province**

Razavi Khorasan

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MalekiM@mums.ac.ir

**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**

70

**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

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Masoud Maleki

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Masoud Maleki

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Naeimeh Ebrahimabadi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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**Province**

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**Postal code**

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**Phone**

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**Email**

EbrahimAbadiN961@mums.ac.ir

## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The consent of the participants is subject to the non-publication of their information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable