

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Evaluation of the effectiveness of oral dapson with intralesional antimoniate in treatment of cutaneous leishmaniasis in comparison with intralesional antimoniate alone

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of oral dapson with intralesional antimoniate in treatment of cutaneous leishmaniasis in comparison with intralesional antimoniate alone

##### Design

This randomized clinical trial has control group, parallel groups without blinding and is carried out on 100 patients with cutaneous leishmaniasis

##### Settings and conduct

100 patients referring to Cutaneous Leishmaniasis Clinics of Imam Reza and Ghaem Hospitals are selected, whose diagnosis with cutaneous leishmaniasis is confirmed using direct smear and have not received any treatment for their disease and are randomly assigned to two groups of intervention and control.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : positive direct smear of the lesion in terms of leishman bodies, less than six month has elapsed since the manifestation of lesion, patient has not received any previous treatment for cutaneous leishmaniasis, location of lesion is either on upper limbs or face. Exclusion criteria : sensitivity to glucantime (severe topical reaction, anaphylaxis), existence of secondary infection in lesion, dapson side effects including methemoglobinemia, hemolytic anemia, agranulocytosis, peripheral neuropathy, hypersensitivity

##### Intervention groups

Intervention group : weekly intralesional injection of glucantime starts for 6 weeks in addition to 1 mg/kg of oral dapson daily and in the case that primary control tests are normal, dapson dosage will increase to 2 mg/kg. Control group : treatment is carried out with weekly intralesional glucantime injection for 4-8 weeks.

##### Main outcome variables

evaluation and comparison of the course of response to therapy and rate of recovery after initiation of treatment.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140211016554N4**

Registration date: **2019-04-28, 1398/02/08**

Registration timing: **retrospective**

Last update: **2019-04-28, 1398/02/08**

Update count: **0**

##### Registration date

2019-04-28, 1398/02/08

##### Registrant information

##### Name

Vahid Mashayekhi-Goyonlo

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3802 2490

##### Email address

mashayekhiv@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2013-01-20, 1391/11/01

##### Expected recruitment end date

2014-08-01, 1393/05/10

##### Actual recruitment start date

2012-06-12, 1391/03/23

##### Actual recruitment end date

2014-09-17, 1393/06/26

**Trial completion date**

2014-09-17, 1393/06/26

**Scientific title**

Evaluation of the effectiveness of oral dapson with intralesional antimoniate in treatment of cutaneous leishmaniasis in comparison with intralesional antimoniate alone

**Public title**

Evaluation of the effectiveness of oral dapson with intralesional antimoniate in treatment of cutaneous leishmaniasis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

positive direct smear of the lesion in terms of leishman bodies patient has indication of topical treatment according to the physician less than six month has elapsed since the manifestation of lesion patient has not received any previous treatment for cutaneous leishmaniasis intervention group has normal values for CBC;G6PD;LFT location of lesion is either on upper limbs or face

**Exclusion criteria:**

sensitivity to glucantime (severe topical reaction, anaphylaxis). absence of regular follow-ups existence of secondary infection in lesion use of other treatments during the study dapson side effects including methemoglobinemia, hemolytic anemia, agranulocytosis, peripheral neuropathy, hypersensitivity

**Age**

From **10 years** old to **40 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

Actual sample size reached: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, simple randomization will be carried out using table of random numbers produced by a computer.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**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**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

900689

**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**

Change in size of the lesion

**Timepoint**

At the end of each week

**Method of measurement**

based on lesion induration measured by a caliper

**Secondary outcomes**

1

**Description**

side effects

**Timepoint**

weekly

**Method of measurement**

clinical evaluation

**Intervention groups**

1

**Description**

In control group, patients receive intralesional

glucantime injection weekly for 4-8 weeks.

### Category

Treatment - Drugs

## 2

### Description

In intervention group, weekly intralesional injection of glucantime starts for 6 weeks in addition to 1 mg/kg of oral dapson daily and in the case that primary control tests are normal, dapson dosage will increase to 2 mg/kg.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology clinic, Imam Reza Hospital

##### Full name of responsible person

Vahid Mashayekhi

##### Street address

Imam Reza Hospital, Imam Reza square, Ebn\_e\_sina Avenue

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3802 2020

##### Email

mashayekhiv@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Dermatology clinic, Ghaem Hospital

##### Full name of responsible person

Azadeh Mohammadi

##### Street address

Ghaem Hospital, Ahmad Abad Avenue

##### City

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##### Province

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##### Postal code

9176699199

##### Phone

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghodi

##### Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

##### City

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##### Province

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##### Email

ramresearch@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

100

#### 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

Azadeh Mohammadi

##### Position

dermatologist

##### Latest degree

Specialist

##### Other areas of specialty/work

Dermatology

##### Street address

Ghaem Hospital, Ahmad Abad Street

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##### Province

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**Email**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Vahid Mashayekhi-Goyonlo

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Vahid Mashayekhi-Goyonlo

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Imam Reza Hospital, Imam Reza square, Ebn\_e\_sina Avenue

Avenue

**City**

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**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3802 2020

**Fax****Email**

mashayekhiv@mums.ac.ir

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data can be shared after patients are made unidentifiable.

**When the data will become available and for how long**

Data can be accessible 6 months after results are published.

**To whom data/document is available**

Data will be available for researchers in universities and other scientific institutes.

**Under which criteria data/document could be used**

Carrying out analysis on data is permitted.

**From where data/document is obtainable**

Data can be accessible through sending an email to the corresponding author.

**What processes are involved for a request to access data/document**

After sending a request email to the corresponding author, data will be sent in 1 month.

**Comments**