Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

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

Protocol summary

Study aim
Evaluation of the effectiveness of oral dapsone 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 Leishmanaisis Clinics of Imam Reza and Ghaem Hospitals are selected, whose diagnosis with cutaneous leishmanaisis 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, dapsone 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 dapsone 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)

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+98 51 3802 2490

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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 dapsone with intralesional antimoniate in treatment of cutaneous leishmaniasis in comparison with intralesional antimoniate alone

Public title

Evaluation of the effectiveness of oral dapsone 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 dapsone 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

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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 dapsone 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 Raza Hospital

Full name of responsible person

Vahid Mashayekhi

Street address

Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue

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2

Recruitment center

Name of recruitment center

Dermatology clinic, Ghaem Hospital

Full name of responsible person

Azadeh Mohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Mohsen Tafaghodi

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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

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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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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