

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The Effect of Berberis Vulgaris hydro alcoholic extract, On Cutaneous Leishmaniasis patients in comparison with Glucantime and Placebo: A Clinical Trial

Protocol summary

Summary

Objective: Evaluation of the effect of Berberis Vulgaris extract, on Cutaneous Leishmaniasis Specific Objectives: 1-Frequency of age, sex, lesion size, number of lesion, lesion site, lesion kind, leishmania spp. 2- Cure rate in different kind of Cutaneous Leishmaniasis treated by Barberry extract. 3- Cure rate comparison between group 1&2&3. 4- Adverse effect in interventional groups and comparison of them that infected by L. Major and L. Tropica. 5- Cure time comparison between 3 groups. 6- To determine the cure rate in ulcerated and no ulcerated lesions in 3 groups 7- To determine the cure rate on the basis of duration of disease, lesion site, age and sex in the study groups. Location: University's Cutaneous leishmaniasis clinics in Mashhad and Torghabeh Implementation and interventions: the volunteers were divided into 3 groups: Group 1 (whom received topical Barberry extract), Group 2 (whom received topical Barberry extract & intralesional Glucantime), Group 3 (whom received topical Placebo & intralesional Glucantime). Duration of treatment: 8 weeks. Follow up: weekly until 8th weeks. Then 14th week and 3 month after termination of treatment. Inclusion criteria: age $\geq$ 12 years, the number of lesions to 5, limbs and trunk lesions except joint. Exclusion criteria: infection, lack of response in 30 days, lack of directives. Then responsiveness classified to 5 grades: Complete response: decrease in induration and ulcer 100% or getting negative skin smear test Significant response: decrease in induration and ulcer between 76-99% Relative response: decrease in induration and ulcer between 51-75% Partial response: decrease in induration and ulcer between 26-50% Failure: decrease in induration and ulcer $<$ 26%

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060122512N1**
Registration date: **2017-06-19, 1396/03/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-19, 1396/03/29

Registrant information

Name

Masoud Maleki

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2510

Email address

malekim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-02-18, 1393/11/29

Expected recruitment end date

2016-02-18, 1394/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
Scientific title	City
The Effect of Berberis Vulgaris hydro alcoholic extract, On Cutaneous Leishmaniasis patients in comparison with Glucantime and Placebo: A Clinical Trial	Mashhad
Public title	Postal code
The effect of Berberis Vulgaris extract, on Cutaneous Leishmaniasis	Approval date
Purpose	2014-12-03, 1393/09/12
Treatment	Ethics committee reference number
Inclusion/Exclusion criteria	IR.MUMS.REC.1393.201
Inclusion criteria: Presence of cutaneous leishmaniasis with less than 6 months of clinical course; Not receive any treatment 3 months before; Age 8 years and above; Lesion diameter less than 3 cm; The number of lesion less than 5; The lesion on the limbs and trunk with the exception of joints' surface. Exclusion criteria: Pregnancy; Lactating; Receiving simultaneous treatment with other methods during treatment course; History of significance renal, Pulmonary and cardiovascular disease; Create a secondary infection of the wound; Deterioration of the condition of the patient during the study; Immune suppressor drugs consumption; Do not run commands therapy.	Health conditions studied
Age	<u>1</u>
From 12 years old	Description of health condition studied
Gender	Cutaneous Leishmaniasis
Both	ICD-10 code
Phase	B55.1
3	ICD-10 code description
Groups that have been masked	Cutaneous Leishmaniasis
No information	Primary outcomes
Sample size	<u>1</u>
Target sample size: 120	Description
Randomization (investigator's opinion)	Lesion size change
Randomized	Timepoint
Randomization description	Weekly until 8 weeks
Blinding (investigator's opinion)	Method of measurement
Not blinded	Measuring the size of induration and ulcer by caliper
Blinding description	Secondary outcomes
Placebo	<u>1</u>
Used	Description
Assignment	Side effects: erythema, itching
Parallel	Timepoint
Other design features	Weekly
Secondary Ids	Method of measurement
empty	Clinical evaluation
Ethics committees	Intervention groups
<u>1</u>	<u>1</u>
Ethics committee	Description
Name of ethics committee	Intervention group: topical use of Berberis Vulgaris extract three times daily for 8 weeks
Ethics Committee of Mashhad University of Medical Sciences	Category
Street address	Treatment - Drugs
Central Building of Mashhad University of Medical Sciences	<u>2</u>
	Description
	Intervention group: injection of intralesional Glucantime weekly for 8 weeks and topical use of Berberis Vulgaris extract three times daily for 8 weeks
	Category
	Treatment - Drugs

3

Description

Control group: injection of intralesional meglumine antimoniate (glucantime) weekly for 8 weeks and topical use of placebo three times daily for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cutaneous Leishmaniasis Research center, Mashhad University of Medical Sciences

Full name of responsible person

Dr Gholam Reza Haghighi

Street address

Vakil Abad St. Faculty of Traditional Medicine

City

Mashhad

2

Recruitment center

Name of recruitment center

Health Center of haft-e tir

Full name of responsible person

Dr Gholam Reza Haghighi

Street address

Vakil Abad St. Faculty of Traditional Medicine

City

Mashhad

3

Recruitment center

Name of recruitment center

Health Center of shahrak-e lashkar

Full name of responsible person

Dr Gholam Reza Haghighi

Street address

Vakil Abad St. Faculty of Traditional Medicine

City

Mashhad

4

Recruitment center

Name of recruitment center

Health Center of Nejati

Full name of responsible person

Dr Haghighi Gholamreza

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City

Mashhad

5

Recruitment center

Name of recruitment center

Health unit of Chaheshk

Full name of responsible person

Dr Gholamreza Haghighi

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Vakil Abad St. Faculty of Traditional Medicine

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

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

City

Mashhad

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, Vice Chancellor for Research

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

Dermatology Department & Cutaneous Leishmaniasis Research Center, Mashhad University of Medical Scie

Full name of responsible person

Dr Masoud Maleki

Position

Professor of dermatology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Bachelor of Biology

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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