Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 sixe, 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 detemine 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 recived 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 mounth after termination of treatment. Inclusion criteria: age≥ 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)
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+98 51 3802 2510
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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

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

Public title
The effect of Berberis Vulgaris extract, on Cutaneous Leishmaniasis

Purpose
Treatment

Inclusion/Exclusion criteria
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.

Age
From **12 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
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

Postal code

Approval date
2014-12-03, 1393/09/12

Ethics committee reference number
IR.MUMS.REC.1393.201

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 size change

Timepoint
Weekly until 8 weeks

Method of measurement
Measuring the size of induration and ulcer by caliper

Secondary outcomes

1

Description
Side effects: erythema, itching

Timepoint
Weekly

Method of measurement
Clinical evaluation

Intervention groups

1

Description
Intervention group: topical use of Berberis Vulgaris extract three times daily for 8 weeks

Category
Treatment - Drugs

2

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
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3

Recruitment center
Name of recruitment center
Health Center of shahrak-e lashkar
Full name of responsible person
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Street address
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4

Recruitment center
Name of recruitment center
Health Center of Nejati
Full name of responsible person
Dr Haghighi Gholamreza
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5

Recruitment center
Name of recruitment center
Health unit of Chaheshk
Full name of responsible person
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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
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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, 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
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Professor of dermatology
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Person responsible for scientific inquiries

Contact

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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