

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation Leish G1 cream efficacy on healing the cutaneous leishmaniasis

Protocol summary

Study aim

Evaluating efficiency of a topical medication based on garlic extract (Leish G1 cream) on cutaneous leishmaniasis

Design

A clinical trial, phase 3, 2 groups of control and intervention, each group has 50 patients

Settings and conduct

Patients who refer to health centers and specialized clinics in several cities in the south and west of the country are examined to approve leishmaniasis diagnose. After signing consent form, patients are assigned to either control or intervention group. Follow up and examination is done to determine the correct use of the drug and possible side effects and complete the questionnaire on days 1, 14, 28 and 60. On the 60th day, a test is performed again to evaluate wound healing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Cutaneous leishmaniasis approved by direct examinations Up to 5 lesions in each patient Duration of disease up to 3 months Patients who have not used anti leishmania therapies Exclusion criteria: Patients with Facial lesions Patients with Lymphangitis lesions Patients with Immunodeficiency disorders Patients who use immunosuppressive drugs Patients with other skin diseases Patients with severe mental disorders Concomitant use of other medication Pregnancy or lactation

Intervention groups

Intervention group: Topical use of Leish G1 cream on leishmanial lesions twice daily for two months. The medication is a formulation of aquas garlic extract Control group: Meglumine Antimonate intralesional injection once weekly

Main outcome variables

Wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180115038383N1**

Registration date: **2018-02-08, 1396/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-08, 1396/11/19**

Update count: **0**

Registration date

2018-02-08, 1396/11/19

Registrant information

Name

Tooba Ghazanfari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6642 6890

Email address

ghazanfari@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Leish G1 cream efficacy on healing the cutaneous leishmaniasis

Public title

Effect of Leish G1 cream in leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Cutaneous leishmaniasis approved by direct examinations Up to 5 lesions in each patient Duration of disease up to 3 months Patients who have not used anti leishmaniasis therapies

Exclusion criteria:

Patients with facial lesions Patients with Lymphangitis lesions Patients with Immunodeficiency disorders Patients who use immunosuppressive drugs Patients with other skin diseases such as Eczema, Psoriasis and Lupus Patients with severe mental disorders such as Major Depressive Disorder and Psychosis Concomitant use of other medications Pregnancy or lactation

Age

From **12 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Shahed University of Medical Sciences

Street address

Khalij Fars Freeway, across Imam khomeini shrine

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-01-08, 1396/10/18

Ethics committee reference number

IR.Shahed.REC.1396.77

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**

Wound healing

Timepoint

Evaluating size and grade of cutaneous lesion in days 0, 14, 28 and 60 after treatment

Method of measurement

Ruler

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Topical use of Leish G1 cream on leishmanial lesions twice daily for two months. The medication is a formulation of aquas garlic extract based on Eucerin, formulated in Behpad Teb Iranian laboratory and produced in Dineh Iran Industries complex.

Category

Treatment - Drugs

2**Description**

Control group: Meglumine Antimonate intralesional injection once weekly

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mehri Ghafourian
Street address
Ahvaz Jundishapur University of Medical Sciences
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6135715794
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2

Recruitment center

Name of recruitment center
Dezfool University of Medical sciences
Full name of responsible person
Abdolkarim Sheikhi
Street address
Research center, Dezfofl university of medical sciences, Azadegan Blvd, Azadegan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University
Full name of responsible person
Tooba Ghazanfari
Street address
Khalij Fars Freeway, across Imam khomeini shrine
City
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3319118651
Phone
+98 21 6641 8216
Email
ghazanfari@shahed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes
Title of funding source
Shahed University
Proportion provided by this source
40
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

2

Sponsor

Name of organization / entity
Behpad Teb Iranian
Full name of responsible person
Soosan Kaboodanian Ardestani
Street address
No 37, West Nosrat, North Kargar, Enghelab Squar
City
Tehran
Province
Tehran
Postal code
1418863981
Phone
+98 21 6642 6890
Email
ardestany@ut.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Behpad Teb Iranian

Proportion provided by this source

60

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Shahed University
Full name of responsible person
Fateme Emadi
Position
Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacognosy

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

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Full name of responsible person

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

Shahed University

Full name of responsible person

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Latest degree

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Other areas of specialty/work

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

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

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

After publishing the final results, the study protocol, statistical analyzes and consent form will be shared without mentioning the names of the individuals.

When the data will become available and for how long

6 months after publishing results

To whom data/document is available

Iranian researchers

Under which criteria data/document could be used

To design review articles, statistical analysis and bioinformatics studies

From where data/document is obtainable

Study executor with permission of Shahed university research center

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

Written request to the Study executor Refer to the Research Center at Shahed University Getting research center approval access to data

Comments