

# 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  
**City**  
Ahvaz  
**Province**  
Khouzestan  
**Postal code**  
6135715794  
**Phone**  
+98 61 3336 7543  
**Fax**  
+98 61 3333 2036  
**Email**  
ghafourian-m@ajms.ac.ir

## 2

### **Recruitment center**

**Name of recruitment center**  
Dezfool University of Medical sciences  
**Full name of responsible person**  
Abdolkarim Sheikhi  
**Street address**  
Research center, Dezfool university of medical sciences, Azadegan Blvd, Azadegan  
**City**  
Dezfool  
**Province**  
Khouzestan  
**Postal code**  
6461643993  
**Phone**  
+98 61 4242 9733  
**Email**  
sheikhi@queensu.ca

## **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**  
Tehran  
**Province**  
Tehran  
**Postal code**  
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

**Street address**

No 1471, North Kargar Street, Enghelab Squar

**City**

Teharn

**Province**

Tehran

**Postal code**

1417953842

**Phone**

+98 21 6646 4320

**Email**

f.emadi@shahed.ac.ir

**Person responsible for scientific 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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Teharn

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Tehran

**Postal code**

1417953842

**Phone**

+98 21 6646 4320

**Email**

f.emadi@shahed.ac.ir

**Person responsible for updating data****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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**Postal code**

1417953842

**Phone**

+98 21 6646 4320

**Email**

f.emadi@shahed.ac.ir

**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**