

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The use of leech to treat patients with cutaneous leishmaniasis in Kerman province.

#### Protocol summary

##### Study aim

To determine the effect of leech on the wound treatment of cutaneous leishmaniasis 1. Determining the time required for the complete healing of a cutaneous leishmaniasis wound 2. Determining the number of times of leech therapy for complete recovery of cutaneous leishmaniasis wound 3. Determining the rate of wound healing one month, six months and one year after leech therapy 4. Determining the diameter of the wound before and after each leech treatment

##### Design

for the intervention of patients who have had treatment resistance to glucantim or other drugs or have had treatment failure. Sterile bred leeches are used for patients five times with intervals of 2 weeks and one month. Patients are followed up at intervals of three months until complete healing of the wound. Healing of the lesion in patients under leech therapy is followed up. do not show recurrence. consent is obtained from all patients who enter the study.

##### Settings and conduct

The intervention is carried out using 5 leeches in 4 to 5 sessions at intervals of 2 to 4 weeks. leeches were placed on the wounds for 30 to 45 minutes to extract 5 to 6 ml of blood. Photographs were taken of the lesions before leech therapy sessions. Sterile leeches were used for patients five times with 2-week and one-month intervals. Patients were followed up at three-month intervals until complete wound healing. The recovery of the lesion is followed up to prevent recurrence. Written informed consent is obtained from all patients who enter the study.

##### Participants/Inclusion and exclusion criteria

It is used for patients who have resistance to glucantim or other drugs or have failed treatment There are minor contraindications for leech therapy such as acute infections, severe anemia, allergies, hemophilia, immunosuppression, skin malignancy, hypotension, and pregnancy.

##### Intervention groups

Leishmaniasis

##### Main outcome variables

Complete healing

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211211053349N3**

Registration date: **2022-12-25, 1401/10/04**

Registration timing: **prospective**

Last update: **2022-12-25, 1401/10/04**

Update count: **0**

##### Registration date

2022-12-25, 1401/10/04

##### Registrant information

##### Name

Leila ShiraniBidabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5053

##### Email address

lshiranibidabadi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-05, 1401/10/15

##### Expected recruitment end date

2023-12-21, 1402/09/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The use of leech to treat patients with cutaneous leishmaniasis in Kerman province.

**Public title**

Leech treatment of Leishmaniasis lesion

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Rural cutaneous leishmaniasis patient Cutaneous leishmaniasis patients who have failed standard Glucantim treatment are included in the study

**Exclusion criteria:**

Acute infections severe anemia allergy hemophilia Immune system suppression Skin malignancy Low blood pressure pregnancy Anemia Diabetes Type 1 Allergy to insect bites

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **2**

More than 1 sample in each individual

Number of samples in each individual: **1**

A sore on the hand or foot

**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**

REC.KMU.I

**Street address**

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2022-12-21, 1401/09/30

**Ethics committee reference number**

375.1401.REC.KMU.I

**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 time

**Timepoint**

Week

**Method of measurement**

Week

**2****Description**

Duration of infection

**Timepoint**

Week

**Method of measurement**

Week

**3****Description**

Complete healing of the wound

**Timepoint**

Week

**Method of measurement**

Week

**Secondary outcomes****1****Description**

Wound recurrence

**Timepoint**

Week

**Method of measurement**

Week

## Intervention groups

### 1

#### Description

Intervention group: Patients who have failed standard glucantim therapy are included in the study. The intervention is performed using 5 leeches in 4 to 5 sessions at intervals of 2 to 4 weeks. In each session, leeches are placed on the wounds for 30 to 45 minutes to extract 5 to 6 ml of blood. Lesions are photographed before leech treatment sessions. sterile leeches are bred and used for patients five times with intervals of 2 weeks and one month. Patients are treated at intervals of three months. Once followed up, they are followed up until complete healing of the wound. The conditions of the patients under leech therapy are followed up so that they do not show recurrence.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Salak Shahid Davari Center

##### Full name of responsible person

Dr Leila Shirani-Bidabadi

##### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran  
Postal Code: 7616913555 Phone : 009834 31325135  
Fax : 009834 31325134

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 913 219 6482

##### Fax

##### Email

Ishiranibidabadi@gmail.com

##### Web page address

<https://sph.kmu.ac.ir/en>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Vice President of Research and Technology

##### Street address

Kerman, the beginning of Haft Bagh Alavi axis,  
University of Medical Sciences campus

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 913 219 6482

##### Email

Ishiranibidabadi@gmail.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Kerman 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

Kerman University of Medical Sciences

##### Full name of responsible person

Leila Shirani-Bidabadi

##### Position

Academic staff

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Entomology

##### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran  
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##### City

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##### Province

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##### Phone

+98 31 3132 5053

##### Email

Ishiranibidabadi@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kerman University of Medical Sciences

**Full name of responsible person**

Leila Shirani-Bidabadi

**Position**

Academic staff

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Entomology

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**Email**

lshiranibidabadi@gmail.com

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

Yes - There is a plan to make this available

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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

**Title and more details about the data/document**

The part related to the main result or similar can be shared.

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

Researcher and Doctors

**Under which criteria data/document could be used**

To treat patients who have failed other treatments

**From where data/document is obtainable**

Dr Leila Shirani-Bidabadi Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran. Postal Code: 7616913555 Phone : 009834 31325829 Fax : 009834 31325830

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

The requester sends an email to the responsible person

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

Kerman University of Medical Sciences

**Full name of responsible person**

Leila Shirani-Bidabadi

**Position**

Academic staf

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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