Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
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+98 34 3132 5053
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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
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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
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7616913555
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+98 913 219 6482
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lshiranibidabadi@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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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