

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effectiveness of topical Myrrh (*Commiphora myrrha*) product on skin lesion healing in patients infected with *Leishmania major* - A pilot study

Protocol summary

Study aim

Determining the effect of topical product of Myrrh in the healing of the lesion caused by *Leishmania major*

Design

This study conducted as a pilot study with before - after intervention and will run in the leishmaniasis treatment center. 10 patients within the accepted patients who complete informed consent form will be included in the study

Settings and conduct

Study will be run in the leishmaniasis treatment Center in Orzoiyeh city and selected patients will use topical cream of 5% Myrrh on the lesions twice a day for 4 weeks. Patients will be visited weekly by an expert and the lesions will be measured

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Cutaneous leishmaniasis, age 8 to 60 years, Number of lesions less than 5, Ulcer size less than 5 cm, Duration of lesion less than 3 months, Receiving no anti-leishmania treatment remedies during the past 3 months, Completing the informed consent form; Exclusion criteria: Pregnancy and lactating, Patients with underlying diseases and allergy, Lesions on joint, face and sensitive organs, Regional adenopathy.

Intervention groups

Patients will use the topical product containing 5% Myrrh gum in the standard base cream prepared in the comprehensive pharmaceutical laboratory twice a day on the skin lesions in an amount that completely covers the lesion for a period of 4 weeks.

Main outcome variables

Size of wound; Induration of wound; healing time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230903059337N1**

Registration date: **2023-10-07, 1402/07/15**

Registration timing: **prospective**

Last update: **2023-10-07, 1402/07/15**

Update count: **0**

Registration date

2023-10-07, 1402/07/15

Registrant information

Name

Mehdi Shafiei_bafti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3131 5724

Email address

kmushafiei51@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of topical Myrrh

(Commiphora myrrha) product on skin lesion healing in patients infected with Leishmania major - A pilot study

Public title

Effect of Myrrh in treatment of leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Cutaneous leishmaniasis by leishmania major Number of skin lesions less than 5 Ulcer size less than 5 cm Duration of lesions no more than 3 months Receiving no anti-leishmania treatment remedies during the past 3 months Completing the informed consent form

Exclusion criteria:

Pregnancy and lactation Underlying diseases and allergy Lesions on joints, face and sensitive organs Regional adenopathy

Age

From **8 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Medical University Campus, Haft-Bagh Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-07-31, 1402/05/09

Ethics committee reference number

IR.KMU.REC.1402.141

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**

Size of Leishmania lesion

Timepoint

in 0,1,2,3,4,6,8 weeks of treatment

Method of measurement

WoundDesk app

2**Description**

Induration of lesion

Timepoint

in 0,1,2,3,4,6,8 weeks of treatment

Method of measurement

Digital Caliper

3**Description**

Wound healing time

Timepoint

in 0,1,2,3,4,6,8 weeks of treatment

Method of measurement

Counting of weeks

Secondary outcomes

empty

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

Patients will use the topical product containing 5% Myrrh gum in the standard base cream prepared in the comprehensive pharmaceutical laboratory twice a day on the skin lesions in an amount that completely covers the lesion for a period of 4 weeks. This patients will be visited by an expert at the start of treatment and in weeks 1, 2, 3, 4, 6, 8 and induration of lesions and size of wounds will be measured.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Leishmania Treatment Center

Full name of responsible person

Mehdi Shafiei_bafti

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Health Center Office, Khalij-e-fars Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abedin Iranpoor

Street address

Deputy for Research and Technology Building, Ebn-e-Sina St., Jihad Blvd

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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

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

Mehdi Shafiei_bafti

Position

Head of CDC

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Research data can be shared as an Excel file without personal information

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Academic researchers with an official request from the academic center

Under which criteria data/document could be used

For use in statistical analysis by declaring the source of data

From where data/document is obtainable

Leishmaniasis Research Center, Kerman University of Medical Sciences Email: leishmaniasis@kmu.ac.ir

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

Sending an official request to the announced email, that will be answered within a month after receiving

Comments