

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Formulation and standardization of Yazd Meybod ethno-topical preparation made from cotton (*Gossypium herbaceum* L.) to evaluate the effect on cutaneous Leishmaniasis, a randomized, double blind, placebo controlled trial.

Protocol summary

Study aim

Formulation and standardization of Yazd Meybod ethno-topical preparation made from cotton (*Gossypium herbaceum* L.) to evaluate the effect on cutaneous Leishmaniasis, a randomized, double blind, placebo controlled trial.

Design

This study is a single centered, double-blinded, placebo-controlled, randomized clinical trial which is a medical study involving human participants in which neither side knows who's getting the true remedy or placebo that subjects are randomly assigned to by random number table. There are two groups contaminated with cutaneous leishmaniasis that are matched by age and sex.

Settings and conduct

Patients are randomly divided into two groups by a random number table and receive a topical or placebo drug, which will be delivered according to the size of the skin lesion for the duration of the treatment and then to evaluate the healing of their wounds. Periodically, they refer to Nikopour Clinic in Yazd, which is under the supervision of Shahid Sadoughi University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Cannot be using any kind of therapy for leishmaniasis 2-Have no kind of immune deficiency diseases 3-No lesions with a diameter bigger than 3 centimeters 4-No lesions located on the face or joints and have less than 5 lesions 5- Patients with less than 5 ulcers Exclusion criteria: 1-Any severe side effects or allergies 2-Patients that do not apply the remedy daily or perform the protocol correctly

Intervention groups

In this study, two groups randomly receive topical medication or placebo. Each patient receives one

milliliter of medication per square centimeter of lesion for 30 days and should visit on days 5, 10, 20 and 30 and their wounds should be evaluated.

Main outcome variables

The factors reported are sex, age, site, lesion duration, erythema size, induration, ulcer presence and laboratorial smear test result.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220131053899N1**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

Registration date

2022-05-14, 1401/02/24

Registrant information

Name

Ali Mohamad Mosadegh Mehrjardi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3530 1623

Email address

ali.moh.mosadegh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and standardization of Yazd Meybod ethno-topical preparation made from cotton (*Gossypium herbaceum* L.) to evaluate the effect on cutaneous Leishmaniasis, a randomized, double blind, placebo controlled trial.

Public title

Formulation and standardization of Yazd Meybod ethno-topical preparation made from cotton (*Gossypium herbaceum* L.) to evaluate the effect on cutaneous Leishmaniasis, a randomized, double blind, placebo controlled trial.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Cannot be using any kind of therapy for leishmaniasis No lesions with a diameter bigger than 3 centimeters Have no kind of immune deficiency diseases No lesions located on the face or joints and have less than 5 lesions Patients with less than 5 ulcers

Exclusion criteria:

Any severe side effects or allergies Patients that do not apply the remedy daily or perform the protocol correctly

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

using random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a single centered, double-blinded, placebo-controlled, randomized clinical trial which is a medical study involving human participants in which neither side knows who's getting the true remedy or placebo that subjects are randomly assigned to by random number table. There are two groups contaminated with

cutaneous leishmaniasis that are matched by age and sex. The assessors also do not know what medication the patient has received.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran university of medical sciences

Street address

Ghods street, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2022-03-13, 1400/12/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1498

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**

ulcer diameter

Timepoint

30 days after starting treatment

Method of measurement

caliper

Secondary outcomes

empty

Intervention groups

1

Description

Each patient receives one milliliter of medication per square centimeter of lesion multiplication on treatment days plus a bandage to cover the lesion and prevent loss of topical medication. Patients take the drug for 30 days and should visit on days 5, 10, 20 and 30 and their wounds should be evaluated.

Category

Treatment - Drugs

2

Description

Control group: Recipients of topical placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikoopoor clinic

Full name of responsible person

Ali Mohammad Mosadegh

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Motahari

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Yazd

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Web page address

<http://web.ssu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrdad Karimi

Street address

No 27, Sarparast Ave, Taleghani Street, Palestine Square, Tehran

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spm@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Ali Mohammad Mosadegh

Position

PHD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Arman Zargarani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

PHD candidate

Latest degree

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Other areas of specialty/work

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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

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

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

Publishing in an qualified journal

When the data will become available and for how long

in years 2023 to 2024

To whom data/document is available

Public

Under which criteria data/document could be used

referencing

From where data/document is obtainable

Ali Mohammad Mosadegh

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

Official

Comments