

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Assessing the effectiveness of Aloe vera 2% gel in treatment of Cutaneous Leishmaniasis (CL) on the base of Traditional Persian Medicine (TPM)

Protocol summary

Summary

This study will be a randomized double blind clinical trial on 90 patients of cutaneous leishmaniasis which refer to Gonbad Kavous Cutaneous Leishmaniasis Treatment Center in 1394. patients randomly will be divided in two groups: cases and controls. All patients will be underwent standard treatment for cutaneous leishmaniasis (based on national guideline). Cases will give Aloe Vera gel 2 % and controls will give placebo. medication will be continue until the full lesion epithelialization or 4 weeks after last intervention. patient demographic information and morphological information of lesion (including the number of lesions, location, shape, and duration of lesions), the lesions healing and treatment result and clinical data will be recorded at the beginning of the treatment, at the end of the first week, second, third, fourth (and if not cure happened at the end of forth week after the last intervention) wound healing and clinical information (including the size of the lesion, the size of the induration and the epithelialization) will be measured and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101224490N1**
Registration date: **2016-05-03, 1395/02/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-03, 1395/02/14

Registrant information

Name

Omid Mozafari

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2015-11-01, 1394/08/10

Expected recruitment end date

2016-01-05, 1394/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of Aloe vera 2% gel in treatment of Cutaneous Leishmaniasis (CL) on the base of Traditional Persian Medicine (TPM)

Public title

Assessing the effectiveness of Aloe vera 2% gel in treatment of Cutaneous Leishmaniasis (CL) on the base of Traditional Persian Medicine (TPM)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with lesions which lasts more

than 14 days and definitely diagnosed cutaneous leishmaniasis by parasites seen in smears taken from skin lesions, and treating by the national standard treatment guidelines, after complete description of the study, in the case of consent to participate in the study are: Exclusion criteria: pregnant women, patients with allergy to antimuan, patients taking more than three months have passed since the first appearance of skin lesions, patients in recent months any way be used to treat leishmaniasis, patients which their wound on the eyelids, ear, nose or are less than one centimeter is near the end of the lips and eyes

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization will be performed by using the random number tables

Secondary Ids

empty

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Imam square, Joybar threeway, start of Valiye Asr highway, Sari

City

Sari

Postal code**Approval date**

2015-09-30, 1394/07/08

Ethics committee reference number

1751- IR.MAZUMS.REC.94

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**

longest diameter of ulceration area

Timepoint

0,7,14,21,28 day& if not cured 4 week after last intervention

Method of measurement

ruler

2**Description**

longest diameter of Induration area

Timepoint

0,7,14,21,28 day& if not cured 4 week after last intervention

Method of measurement

ruler

3**Description**

Healing rate

Timepoint

0,7,14,21,28 day& if not cured 4 week after last intervention

Method of measurement

observation & calculation

4**Description**

treatment resualt

Timepoint

at the end of treatment, and if lesion not full epithelialized 4 weeks after last intervention

Method of measurement

observation & determination

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

side effect

Timepoint

during treatment

Method of measurement

observation & interview

Intervention groups

1

Description

Intervention group: Aloe vera 2% Gel two times a day a layer until the full lesion epithelialization or up to 4 weeks after last intervention

Category

Treatment - Drugs

2

Description

Control group: Placebo Gel two times a day a layer until the full lesion epithelialization or up to 4 weeks after last intervention

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gonbad kavoos Health Center, Cutaneous Leishmaniasis Treatment Center

Full name of responsible person

Omid Mozafari

Street address

Gonbad Kavooos Health Center

City

Gonbad Kavooos

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

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Imam square, Joybar threeway, start of Valiye Asr highway, Sari

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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

Vice chancellor for research of Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Omid Mozafari

Position

PhD student in Traditional Persian Medicine

Other areas of specialty/work

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Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty