Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Kavoos 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 begining 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)

Phone

+98 17 3322 5124

Email address

dr.mozafari@goums.ac.ir

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 treatmen, 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 Kavoos Health Center
City
Gonbad Kavoos

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
Street address
Imam square, Joybar threeway, start of Valiye Asr highway, Sari
City
Sari
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
Street address
Traditional and Complementary Medicine Research Center, Mazandaran University of Medical Sciences
City
Sari
Postal code
497164885
Phone
+98 11 3324 4893
Fax
Email
dr.mozafari@goums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Syde Sedighe Yosefi
Position
assistant professor
Other areas of specialty/work
Street address
Imam square, Joybar threeway, start of Valiye Asr highway, Sari
City
Sari
Postal code
Phone
+98 11 3324 4893
Fax
+98 11 3324 4893
Email
dr_ssyosefi@yahoo.com
Web page address

Person responsible for updating data

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
Street address
Traditional and Complementary Medicine Research Center, Mazandaran University of Medical Sciences
City
Sari
Postal code
4971684771
Phone
+98 17 3322 5124
Fax
+98 17 3329 4534
Email
dr.mozafari@goums.ac.ir
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