

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Assessing the effectiveness of Sambucus Ebulus ointment in treatment of Leishmaniasis

Protocol summary

Study aim

Determine the effectiveness of Sambucus Ebulus ointment in treatment of Leishmaniasis

Design

This study will be a randomized double blind clinical trial on 90 patients come down with cutaneous leishmaniasis which refer to Gonbad Kavoos Cutaneous Leishmaniasis Treatment Center in 2017-2018. 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 Sambucus Ebulus ointment 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.

Settings and conduct

This study will be a randomized double blind clinical trial on 90 patients come down with cutaneous leishmaniasis which refer to Gonbad Kavoos Cutaneous Leishmaniasis Treatment Center in 2017-2018.

Participants/Inclusion and 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.

Intervention groups

Intervention group: Sambucus Ebulus 5% ointment two times a day a layer until the full lesion epithelialization or up to 4 weeks after last intervention. Control group: Placebo ointment two times a day a layer until the full lesion epithelialization or up to 4 weeks after last intervention.

Main outcome variables

longest diameter of ulceration area; longest diameter of Induration area; Healing rate; treatment resualt will be measured in 0,7,14,21,28 day& if not cured 4 week after last intervention.

General information

Reason for update

Acronym

Leishmaniasis

IRCT registration information

IRCT registration number: **IRCT20171028037044N4**

Registration date: **2018-01-26, 1396/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-26, 1396/11/06**

Update count: **0**

Registration date

2018-01-26, 1396/11/06

Registrant information

Name

Seyde Sedighe Yousefi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3325 2843

Email address

s.yousefi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2017-11-30, 1396/09/09

Expected recruitment end date

2018-02-09, 1396/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of Sambucus Ebulus ointment in treatment of Leishmaniasis

Public title

Assessing the effectiveness of Sambucus Ebulus ointment in treatment of Leishmaniasis

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.

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

- Participant
- Investigator

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed by using the random number tables.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this survey patient and researcher are blind and drug and placebo would coding by Pharmacist.

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

Province

Mazandaran

Postal code

497164885

Approval date

2017-10-14, 1396/07/22

Ethics committee reference number

IR.MAZUMS.REC.1396.2150

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: Sambucus Ebulus 5 % ointment 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 ointment 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, Cutaneous Leishmaniasis Treatment Center

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4818715856

Email

s.yousefi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

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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

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**

Golestan University of Medical Sciences

Full name of responsible person

Omid Mozafari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work**Street address**

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Seyde Sedighe Yousefi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Assistant professor

Latest degree

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Other areas of specialty/work

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Fax**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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