

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparing the effectiveness of Sambucus Ebulus leaf extract ointment and placebo, in treatment results of Cutaneous Leishmaniasis; A double blind clinical trial

Protocol summary

Study aim

Determination of the effect of of Sambucus Ebulus leaf extract ointment in treatment of cutaneous leishmaniasis. Determination of the effect of of Sambucus Ebulus leaf extract ointment in reducing of the diameter of cutaneous leishmaniasis ulcer. Determination of the effect of of Sambucus Ebulus leaf extract ointment in reducing of the diameter of cutaneous leishmaniasis induration. Determination of the effect of of Sambucus Ebulus leaf extract ointment in healing rate of cutaneous leishmaniasis. Determination of the effect of of Sambucus Ebulus leaf extract ointment in treatment results of cutaneous leishmaniasis.

Design

This study will be a randomized double-blind clinical trial on 110 patients of cutaneous leishmaniasis. Patients will be divided into intervention and Control groups based on Simple Random Allocation (random numbers table). Each patient will give a unique code.

Settings and conduct

Patients who are referred to "Cutaneous Leishmaniasis treatment Center" placed in Gonbad kavoos Health Center in 1396 will be studied.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with confirmed cutaneous leishmaniasis diagnosis. Exclusion criteria: pregnant women; patients with allergy to antimuan; patients with lesions lasting more than 3 month; patients whose wound is on the eyelids, ear, nose or are less than one centimeter from the end of the lips and eyes.

Intervention groups

All patients will get treatment based on National guideline. In addition, patients in intervention group will get Sambucus Ebulus leaf extract ointment and controls will get placebo. Medication will be continued until the full lesion epithelialization occurrence or up to 4 weeks.

Main outcome variables

longest diameter of ulceration area; longest diameter of Induration area; Healing rate; treatment result

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151012024490N2**

Registration date: **2018-01-01, 1396/10/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-01, 1396/10/11**

Update count: **0**

Registration date

2018-01-01, 1396/10/11

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

Expected recruitment start date

2017-12-06, 1396/09/15

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of Sambucus Ebulus leaf extract ointment and placebo, in treatment results of Cutaneous Leishmaniasis; A double blind clinical trial

Public title

Effectiveness of Sambucus Ebulus leaf extract ointment in treatment results of Cutaneous Leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with confirmed cutaneous leishmaniasis diagnosis

Exclusion criteria:

pregnant women patients with allergy to antimuan passing more than three months from the first existence of skin lesions getting any treatment for leishmaniasis in recent month patients whose wounds are on the eyelids, ear, nose or near the end of the lips and eyes (less than one centimeter)

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **110****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be randomly divided into 2 groups; cases and controls based on Simple Random Allocation (random numbers table).

Blinding (investigator's opinion)

Double blinded

Blinding description

All cases and controls will get an ointment which looked like in shape, color and smell. And each patient will get an unique code.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Golestan University of Medical Sciences

Street address

Phalsaphy complex, Shast kola Road

City

Gorgan

Province

Golestan

Postal code

4918936316

Approval date

2017-11-28, 1396/09/07

Ethics committee reference number

IR.Goums.REC.13960220

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

At the first, 7th, 14th, 21th, 28th day of the treatment. And at 28th day after last treatment intervention, if the wound doesn't heal within first 4 weeks.

Method of measurement

ruler

2**Description**

longest diameter of Induration area

Timepoint

At the first, 7th, 14th, 21th, 28th day of the treatment. And at 28th day after last treatment intervention, if the wound doesn't heal within first 4 weeks.

Method of measurement

ruler

3**Description**

Healing rate

Timepoint

At the first, 7th, 14th, 21th, 28th day of the treatment.

And at 28th day after last treatment intervention, if the wound doesn't heal within first 4 weeks.

Method of measurement

observation & calculation

4

Description

treatment result

Timepoint

During treatment or during 4 weeks after treatment

Method of measurement

observation & calculation

5

Description

healing rate

Timepoint

During treatment or during 4 weeks after treatment

Method of measurement

observation & calculation

Secondary outcomes

empty

Intervention groups

1

Description

Sambucus Ebulus leaf extract ointment. In order to prepare the ointment, a 5% extract of the plant leaves in vaseline (and liquid paraffin) will be used. This drug will be made at Mazandaran University of Medical Sciences. The ointment will be used twice a day. First the lesion should be washed with water. After drying, a thin layer of ointment should be used and the area should be kept dry for about two hours. It is forbidden to use other medications at the treatment time.

Category

Treatment - Drugs

2

Description

Placebo ointment contains the base compound (Vaseline and liquid paraffin) that will be similar to the drug in shape and smell and only the active ingredient will be absent. This placebo will be made at Mazandaran University of Medical Sciences. The ointment will be used twice a day. First the lesion should be washed with water. After drying, a thin layer of ointment should be used and the area should be kept dry for about two hours. It is forbidden to use other medications at the treatment time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gonbad Kavoos Health Center- Cutaneous Leishmaniasis Treatment Center

Full name of responsible person

Safoora Saberi

Street address

Health Center, Sarabi street.

City

Gonbad Kavoos

Province

Golestan

Postal code

4971684471

Phone

+98 17 3328 8512

Fax

+98 17 3328 8512

Email

dr.mozafari@goums.ac.ir

Web page address

http://goums.ac.ir/index.php?slc_lang=fa&sid=48

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohamadreza Honarvar

Street address

Shast kola

City

Gorgan

Province

Golestan

Postal code

4918936316

Phone

+98 17 3242 1289

Fax

+98 17 3242 1660

Email

honarvar@goums.ac.ir

Web page address

http://goums.ac.ir/index.php?slc_lang=fa&sid=12

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Phone

+98 17 3322 5124

Fax

+98 17 3322 5124

Email

dr.mozafari@goums.ac.ir

Person responsible for general inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Safoora Saberi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Health Center, Sarabi street

City

Gonbad kavoos

Province

Golestan

Postal code

6721611784771

Phone

+98 17 3328 6852

Fax

+98 17 3328 6852

Email

dr.mozafari@goums.ac.ir

Web page address

http://goums.ac.ir/index.php?slc_lang=fa&sid=48

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

Gorgan University of Medical Sciences

Full name of responsible person

Omid Mozafari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

School of medicine, Golestan University of Medical Sciences, Shast kola, Gorgan, Iran

City

Gorgan

Province

Golestan

Postal code

4918936316

Phone

+98 17 3322 5124

Fax

+98 17 3322 5124

Email

dr.mozafari@goums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gorgan University of Medical Sciences

Full name of responsible person

Omid Mozafari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

School of medicine, Golestan University of Medical Sciences, Shast kola, Gorgan, Iran

City

Gorgan

Province

Golestan

Postal code

4918936316

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

Undecided - It is not yet known if there will be 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