

# 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 size**Target 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 Kavvoos Health Center- Cutaneous Leishmaniasis Treatment Center

**Full name of responsible person**

Safoora Saberi

**Street address**

Health Center, Sarabi street.

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**Web page address**

[http://goums.ac.ir/index.php?slc\\_lang=fa&sid=48](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**

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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**

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

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**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

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**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

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

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**Full name of responsible person**

Omid Mozafari

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

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**Province**

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**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