Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the effect of two herbal products (blend of vinegar, Plantago ovata and cotton) in comparison with placebo in patients with standard treatment of leishmaniasis in rural type center.

Protocol summary

Study aim
Evaluation of the effect of two herbal products (blend of vinegar, Plantago ovata and cotton) in comparison with placebo in patients with standard treatment of leishmaniasis in rural type center.

Design
A phase 3 clinical trial with a control group, with parallel, double-blind and randomized groups. Simple random by envelope method. Each group has 44 people.Total 132 people.

Settings and conduct
After approval of herbs and toxicological and microbial tests, medicines are given to patients in similar forms. Patients and health care providers are not aware of the drug content. Full patient and wound characteristics are recorded. Before the start of treatment, the end of the first, second, third, fourth and eighth weeks of wound healing and clinical information (including wound size, induration size, and epithelialization rate) will be measured and recorded. Patients will be taken in Yazd and Ardakan centers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Test positive, age between 6 and 60 years, wound diameter less than 3 cm, 4 lesions and less. Exclusion criteria: Complicated Types, 5 Lesions and Over, Wound Diameter Over 3cm, Lactating and Pregnant Women, Facial Wounds, Sensitivity to Glucantime, Onset of More Than 3 Months, Use of Other Anti-leishmaniosis Medications in the Past Month.

Intervention groups
Patients were randomly divided into three groups of 44 patients. Patients are randomly assigned to one of the following study groups: 1- The group receiving the composition of vinegar and plantago ovata. 2- Receiving group of cotton plant product. 3. Control group. All patients will receive standard treatment for cutaneous leishmaniasis based on the latest national guidelines.

Main outcome variables
The surface of the wound

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191221045845N1**
Registration date: **2020-01-29, 1398/11/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-29, 1398/11/09**
Update count: **0**

Registration date
2020-01-29, 1398/11/09

Registrant information
Name
Sayed Mehrdad Mousavi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-01-15, 1398/10/25
Expected recruitment end date
2020-04-20, 1399/02/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of two herbal products (blend of vinegar, Plantago ovata and cotton) in comparison with placebo in patients with standard treatment of leishmaniasis in rural type center.

Public title

The effect of medicinal plants on the leishmaniosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Proof of cutaneous leishmaniasis through smear The patients should not be less than 6 years old and not more than 60 years old The lesion size should be less than 3 cm The duration of the illness is less than 12 weeks No lesion on the face Not having any other anti-leishmaniasis medication in the past 4 weeks Don't be pregnant or breastfeeding Do not have severe skin disease such as eczema, psoriasis or chronic dermatitis of unknown origin Has no serious, chronic or malignant disease and is not under chemotherapy treatment Has 4 or less lesions in the body No travel history 6 months ago

Exclusion criteria:

The type of cutaneous leishmaniasis may be complicated, with complications such as a patient with mucosal leishmaniasis Having 5 lesions and more Lesions greater than 3 cm Subcutaneous nodules Regional adenopathy larger than 1 cm People with immunodeficiency Children under 6 years Women in Lactation and Pregnancy sporotrichoid leishmaniasis or satellite lesions Patients with ulcers on the face Patients with a history of drug allergy to antimony compounds Patients who have had more than three months since their first skin lesions appeared Patients who have used any method of treatment for cutaneous leishmaniasis during the past month Patients with a history of travel to other areas of leishmaniasis in the past 6 months as well as those of urban leishmaniasis

Age

From **6 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **132**

More than 1 sample in each individual

Number of samples in each individual: **3**

wound

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization envelops shuffling

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the participants and the clinical caregiver, the drugs are labeled with codes 1, 2, and 3 (placebo). The patient and the clinical caregiver and principal investigator are unaware of the type of drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of yazd University of Medical Sciences

Street address

school of Iranian Medicine,Imam Khomeini street, ardekan, yazd

City

yazd

Province

Yazd

Postal code

8951737915

Approval date

2019-10-08, 1398/07/16

Ethics committee reference number

IR.SSU.REC.1398.136

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

Leishmaniasis lesion area

Timepoint

Before treatment and then every week until healing or the eighth week

Method of measurement

Mathematical calculations with mm-square scale

Secondary outcomes

1

Description
Wound healing time
Timepoint
End of treatment
Method of measurement
Time between start and end of treatment in days

Intervention groups

1

Description
Intervention group: Standard treatment plus cream (topical medicinal product) containing extract of cotton plant is administered twice daily for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Standard treatment plus cream (topical medicinal product) containing the combination of plantago ovata and vinegar is given twice daily for 8 weeks.
Category
Treatment - Drugs

3

Description
Control group: Standard treatment plus placebo is given twice daily for 8 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd University of Medical Sciences
Full name of responsible person
Sayed Mehrdad Mousavi
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Sponsors / Funding sources

1

Sponsor
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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
Yazd 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Monitoring information during the study

When the data will become available and for how long
Upon first request or about a week

To whom data/document is available
Applicant's subordinate authorities

Under which criteria data/document could be used
Proof, Understanding and Exploitation

From where data/document is obtainable
Person responsible for updating information

What processes are involved for a request to access data/document
Request the person responsible for the public accountability of the trial

Comments
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