

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the effect of herbal product containing indigo (*Indigofera argentea*), pistachio gum (*pistacia atlantica*) and chia seed (*Salvia hispanica*) in patients with rural cutaneous leishmaniasis based on folk medicine of Sistan and Baluchestan province

Protocol summary

Study aim

Determining the effect of herbal product containing indigo (*Indigofera argentea*), pistachio gum (*pistacia atlantica*) and chia seed (*Salvia hispanica*) based on folk medicine of Sistan and Baluchestan province in patients with rural cutaneous leishmaniasis referred to health centers in Chabahar in 2021-2022

Design

The clinical trial has a control group with parallel double-blind groups. The intervention and control are divided into two groups of 30. Randomization is done by allocating patients to two groups using the randomized permutation block method and in quadruple blocks.

Settings and conduct

Candidates are selected from those who refer to Chabahar health centers who have leishmaniasis ulcers and a doctor's diagnosis with the approval of the laboratory and the inclusion criteria. The dimensions of the wound are determined with a caliper and a camera equipped with the software. For each participant of the control and intervention group, physician, caregiver, nurses and analyst of the control and placebo group, drug packaging and placebo are not recognizable.

Participants/Inclusion and exclusion criteria

Age range 18 - 70 years old; existence of skin ulcers; positive smear and PCR test result; topically injected glucantime treatment; absence of physical diseases such as: liver disease, cardiovascular problems and kidney problems; no pregnancy and lactation; no atypical wounds.

Intervention groups

Both groups receive the main drug. The intervention group received herbal product topically and the control group received placebo twice a day for one month. The wound dimensions were measured before the intervention, on days: 7, 14, 21 and one month after.

Main outcome variables

Evaluation of the effect of herbal product on wound healing process by measuring wound dimensions and area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210905052377N1**

Registration date: **2021-12-15, 1400/09/24**

Registration timing: **prospective**

Last update: **2021-12-15, 1400/09/24**

Update count: **0**

Registration date

2021-12-15, 1400/09/24

Registrant information

Name

Saeidali Bozorgzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3531 5212

Email address

s.bozorgzade@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of herbal product containing indigo (*Indigofera argentea*), pistachio gum (*pistacia atlantica*) and chia seed (*Salvia hispanica*) in patients with rural cutaneous leishmaniasis based on folk medicine of Sistan and Baluchestan province

Public title

Evaluation of the effect of traditional indigo, pistachio gum and chia seeds on leishmaniasis skin wounds

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Wet skin lesions Laboratory diagnosis of positive smear with Giemsa staining Positive PCR test Treated with topical - injectable glucantime Signing the informed consent of the person or his / her guardian

Exclusion criteria:

Lack of physical diseases such as liver disease, cardiovascular problems and kidney problems No pregnancy and lactation No history of leishmaniasis in the past Lack of recurrences and failure of classical treatment No atypical wounds

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by assigning patients to two groups using the permutation random block method in 4 blocks. The random permutation block table for the two groups, based on which patients are assigned to the two groups, is prepared using the R software as follows. (A) is the control group and (B) is the intervention group. B A A A B A A B B A A B B B B A A B B A A B B A B B A A B B A B A A B A A B A A B B A A B A A B B B B A B A A B A

Blinding (investigator's opinion)

Double blinded

Blinding description

Eligible and volunteer patients are randomly divided into two groups of 30 patients. Patients do not know which drug or placebo each member of the group is receiving.

The treating physician, filing staff who measure and monitor the size of the wound, and nursing staff who inject glucantime injections topically and dress the wounds of both groups with medication and placebo are also unable to diagnose the drug and placebo. For standardization and blinding, herbal powder and placebo powder, which is the same color as the standard food coloring of the plant powder, are placed in identical one-gram capsules, and the cans for the capsules are marked similarly and marked with the abbreviations A and B. When consuming the powder, it is taken out of the capsule and with distilled water, it becomes a paste with a firm consistency and the patient's wound is bandaged. At the end, statistical information is given anonymously to the statistician to analyze the information

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2021-11-08, 1400/08/17

Ethics committee reference number

IR.KMU.REC.1400.488

Health conditions studied

1

Description of health condition studied

Leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Rural leishmaniasis skin lesion

Timepoint

Before the intervention and the days (7, 14, 21, 28) and one month after

Method of measurement

With a caliper, two cross diameters of the wound are measured in centimeters. The wound area in terms of square centimeters is calculated by a camera with software.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Simultaneously with the use of the patient's main drug, the compounds of this study, including indigo, coriander gum and chia seeds, after preparation from reputable perfumers in Chabahar, are studied by botanists of the Faculty of Traditional Medicine and the Kerman School of Pharmacy to identify the genus and species. Plant registration in the herbarium of Kerman University of Medical Sciences has been performed by obtaining the herbarium number. Taking UV rays for disinfection is subject to microbial control tests. And after standardization, it is packaged. Due to the fact that the amount of oral consumption of Nile 2 derms is equal to 6.2 grams, coriander gum 2 mesqal is equal to 9 grams and Lesan al-Abal 3 derms is equal to 9.3 grams in traditional medicine texts and the consumption of chia seeds is up to 25 grams. Since the use of some drugs in traditional medicine as powder extracts, first the dough is placed in molds of the desired dimensions and then dried and stored, and when needed and used, the dough is put back on the stand with some water. In the common method of Balochistan region, some of the mixed powder with some water is made into a paste with medium consistency and is placed on the wound and then it is bandaged with a clean cloth. In this study, for standardization and blinding, it was planned that the powder in the amount of 1000 mg be placed in large capsules of 1 g and when used, it is combined with 0.6 cc of distilled water and made into a paste with medium consistency. The amount used for wound dressing is to create a layer the size of a wound with a thickness of three millimeters of the product. Therefore, first the content of each capsule is converted into a paste and then based on the dimensions of the lesion, all or some of it is used. This product is used twice a day for a month.

Category

Treatment - Drugs

2

Description

Control group: This group also receives the main drug similar to the intervention group. Placebo, which is prepared from food powder and matched with the ineffective standard food color of the product, is placed in capsules of the same color and weight. It is exactly the same as the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Chabahar Health Center

Full name of responsible person

Dr. Abdolrasool khedmati

Street address

Comprehensive Health Center No. 4, next to the Emergency Center, Imam Khomeini St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhty

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Fax

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VCR@KMU.AC.IR

Web page address

<http://www.vresearch.kmu.ac.ir>

Grant name

400000218

Grant code / Reference number

00/10/60/218

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

Yes

Title of funding source

Kerman 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

Faculty of Traditional Medicine, Kerman University of Medical Sciences, Haft Bagh Blvd.

City

Kerman

Province

Kerman

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7616913555

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

Kerman University of Medical Sciences

Full name of responsible person

Saeedali Bozorgzade

Position

PhD student in Iranian medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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

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Latest degree

Medical doctor

Other areas of specialty/work

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

Kerman University of Medical Sciences

Full name of responsible person

Hossein Karegar Barzi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address**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

Summary of all personal information that is examined and analyzed for the main, sub-purposes in the relevant tables that are necessary for the publication of articles in foreign and domestic scientific journals are provided. The application form is submitted through their related scientific institutions

When the data will become available and for how long

Six months after the article was published

To whom data/document is available

The data will be accessible to researchers upon request

through the relevant science center, and industrialists upon request through the relevant authorities.

Under which criteria data/document could be used

For use in scientific research with reference

From where data/document is obtainable

Saeidali Bozorgzade S.bozorgzade@kmu.ac.ir

What processes are involved for a request to access data/document

After receiving the request and coordination with the supervisor and research assistant of Kerman University of Medical Sciences, the materials will be sent.

Comments