

# 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.

#### **City**

Chabahar

#### **Province**

Sistan-va-Balouchestan

#### **Postal code**

9971855531

#### **Phone**

+98 54 3531 2413

#### **Email**

gmail.com@0096

#### **Web page address**

<https://www.irshums.ac.ir>

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Kerman University of Medical Sciences

#### **Full name of responsible person**

Dr. Abbas Pardakhty

#### **Street address**

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#### **Province**

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#### **Postal code**

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#### **Phone**

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#### **Fax**

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#### **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**

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**Postal code**

7616913555

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31326161 34 0098

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**Web page address**

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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

**Street address**

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

Kerman University of Medical Sciences

**Full name of responsible person**

Saeidali bozorgzade

**Position**

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**Latest degree**

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**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**