

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Clinical trial of comparison of Electrotherapy and intralesional injection of Glucantime in the treatment duration of Coetaneous Leishmaniasis

#### Protocol summary

##### Summary

Objectives: Comparison of Electrotherapy and intralesional injection of Glucantime in the treatment of Coetaneous Leishmaniasis Design: Not blinded randomized clinical trial Setting and conduct: 60 patients with Cutaneous Leishmaniasis were randomly divided into two groups. In intervention group(n=30) Electrotherapy was performed and control group(n=30) were treated with intralesional injection of Glucantime Major Inclusion and Exclusion criteria: Inclusion criteria: the lack of local or systemic treatment for Cutaneous Leishmaniasis; the appearance of skin lesions is less than 12 weeks ago. Exclusion criteria: age less than 2 years, previous history of cutaneous leishmaniasis; pregnant or lactating women; malnutrition and underlying severe disease; contraindications for drug administration. Intervention: Electrotherapy was performed once a week in the intervention group and the control group were treated with intralesional injection of Glucantime twice a week. Main outcome measures(variables): Lesion size, secretion, inflammation and blister.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2016011822583N3**

Registration date: **2016-02-28, 1394/12/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-02-28, 1394/12/09

##### Registrant information

**Name**

Mohsen Shoja

##### Name of organization / entity

Esfarayen Faculty of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 85 3722 2469

##### Email address

mohsenshoja61@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of North Khorasan University of Medical Sciences

##### Expected recruitment start date

2013-08-23, 1392/06/01

##### Expected recruitment end date

2015-01-20, 1393/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of comparison of Electrotherapy and intralesional injection of Glucantime in the treatment duration of Coetaneous Leishmaniasis

##### Public title

Comparison of Electrotherapy and intralesional injection of Glucantime in the treatment of Coetaneous Leishmaniasis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: the lack of local or systemic treatment for Cutaneous Leishmaniasis; the appearance of skin lesions is less than 12 weeks ago. Exclusion criteria: age

less than 2 years; previous history of Cutaneous Leishmaniasis; pregnant or lactating women; malnutrition and underlying severe disease; contraindications for drug administration.

#### **Age**

From **2 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of North Khorasan University of Medical Sciences

###### **Street address**

North Khorasan University of Medical Sciences, Shahriar Street, Bojnurd, North Khorasan

###### **City**

Bojnurd

###### **Postal code**

##### **Approval date**

2013-08-19, 1392/05/28

##### **Ethics committee reference number**

673/92 /پ

### **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**

Size of lesion

##### **Timepoint**

Once a week

##### **Method of measurement**

Ruler

#### **2**

##### **Description**

Recovery time

##### **Timepoint**

Once a week

##### **Method of measurement**

Clinical observation

### **Secondary outcomes**

#### **1**

##### **Description**

Inflammation

##### **Timepoint**

Once a week

##### **Method of measurement**

Clinical observation

#### **2**

##### **Description**

Blisters around the lesion

##### **Timepoint**

Once a week

##### **Method of measurement**

Clinical observation

#### **3**

##### **Description**

Secretion of the lesion

##### **Timepoint**

Once a week

##### **Method of measurement**

Clinical observation

### **Intervention groups**

#### **1**

##### **Description**

The Electrotherapy was performed in the intervention group once per week. The lesion was received an electric current with 40 volts and 5-15 ampere for 10 minutes.

##### **Category**

Treatment - Other

## 2

### Description

In the control group, Glucantime ampoule(5ml) were injected intralesional, twice a week and was continued until around the lesion was white.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Esfarayen health center

##### Full name of responsible person

Alireza Akrami

##### Street address

Esfarayen health center, Taleghani Street, Esfarayen, North Khorasan

##### City

Esfarayen

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of North Khorasan University of Medical Sciences

##### Full name of responsible person

Mahdi Bakhsh Abadi

##### Street address

North Khorasan University of Medical Sciences, Shahriar Street, Bojnurd, North Khorasan

##### City

Bojnurd

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice Chancellor for research of North Khorasan University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Esfarayen faculty of Medical Sciences

#### Full name of responsible person

Mohsen Shoja

#### Position

MSc of Epidemiology

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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Post Graduate

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*