

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison Between the Effect of Nd: YAG Laser and Glucantime on Treatment of Cutaneous Leishmaniasis

#### Protocol summary

##### Summary

This study, which is performed as clinical experimentation, is regarding Leishmaniasis. The samples were selected from among the leishmaniasis patients who visited the 17 Shahrivar Hygiene and Treatment Center in Ahwaz. In the first session, two separate leishmanial injuries are specified on the patient's body. The two injuries are subjected to clinical examination. The rate of induration was determined and a score of 1 to 5 was assigned by the examiner (a dermatology assistant). Then each injury was treated using one of the following two methods: A: To one of the injuries, Meglumine antimony is injected using a 1 cc insulin syringe. The maximum injection amount in each session is 1-2 cc. The injection is repeated weekly until the complete improvement of the injury, with a maximum of 10 injections. B: The other injury is subjected to laser treatments (AlexandritLtroni, Nd-YAG, and flow index of 220 J). Treatment with Nd-YAG is repeated in 2-week intervals until complete improvement (no indurations). (Maximum 5 treatment sessions.) In every treatment session, each injury is photographed and the rate of in duration is assigned a score of 1 to 5 by the examiner. After 10 weeks from the start of the treatment, the treatments are stopped and the above information is registered again. Follow-up of the skin injuries is performed after improvement and 3 months later. In each follow-up session, the injury is examined with regards to the scar and PIH, and photographed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017042911363N2**

Registration date: **2017-06-09, 1396/03/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-09, 1396/03/19

##### Registrant information

###### Name

Hannaneh Davoodzadeh

###### Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1373 8255

###### Email address

davoodzadeh.h@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research of Ahwaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2017-05-05, 1396/02/15

##### Expected recruitment end date

2017-10-23, 1396/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison Between the Effect of Nd: YAG Laser and Glucantime on Treatment of Cutaneous Leishmaniasis

##### Public title

Comparison Between the Effect of Nd: YAG Laser and Glucantime on Treatment of Cutaneous Leishmaniasis

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Being 5 to 55 years of age; having at least two leishmanial injuries (leishmaniasis is defined as having a clinical injury according to Cutaneous leishmaniasis along with positive smear test regarding leishmanial body confirmed by a pathologist. Exclusion criteria: Being pregnant or nursing; receiving any prior treatments (including medical or cryotherapy or laser or other destructive methods).

### **Age**

From **5 years** old to **55 years** old

### **Gender**

Both

### **Phase**

4

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

*No information*

### **Sample size**

Target sample size: **10**

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

N/A

### **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**

Ahvaz Jundishapur University of Medical Sciences

##### **Street address**

Ahvaz Jundishapur University of Medical Sciences,  
Golestan Boulevard, Ahvaz, Iran

##### **City**

Ahvaz

##### **Postal code**

#### **Approval date**

2016-12-03, 1395/09/13

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

IR.AJUMS.REC.1395.540

## **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**

Complete improvement of the injury

#### **Timepoint**

At the end of every session, 10 weeks after start of treatment, and 3 months after improvement

#### **Method of measurement**

Measuring the induration and the size of the injury

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 2: The other injury is subjected to laser treatments (AlexandritLtroni, Nd-YAG, and flow index of 220 J).

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group 2: To one of the injuries, Meglumine antimony is injected using a 1 cc insulin syringe. The maximum injection amount in each session is 1-2 cc. The injection is repeated weekly until the complete improvement of the injury, with a maximum of 10 injections.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Ahvaz 17th Shahrivar Center

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

Mohammad Omidian

##### **Street address**

Ahvaz Jundishapur University of Medical Sciences,  
Golestan Boulevard, Ahvaz, Iran

##### **City**

Ahvaz

## **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr Saaki Naader

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz, Iran

**City**

Ahvaz

**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 Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Maryam Jad Babai

**Position**

Dermatologist

**Other areas of specialty/work****Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan Boulevard, Ahvaz, Iran

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Mohammad Omidian

**Position**

Dermatologist

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### Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work****Street address**

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### 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*