

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Evaluating the effect of combination of fractional 1550nm laser therapy plus Sina-ampholeish ointment on cutaneous leishmaniasis

#### Protocol summary

##### Study aim

Finding new, effective and low-risk therapies for cutaneous leishmaniasis

##### Design

Parallel case control nonrandom, non-blinded clinical trial on 65 patients with skin leishmaniasis

##### Settings and conduct

Patients of 5-60 years old having multiple smear positive cutaneous leishmaniasis lesions referred to referral clinic in Fasa city were selected. The main three features of lesions that worth the investigation are the size of the wound, induration and the size of the lesion. Cases will be treated with Sina-Ampholish ointment followed by fractional 1550nm laser. This three feature is assessed before treatment and weekly for 6 weeks during treatment and then 4 weeks after treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Disease duration of Less than 1 months; Written informed consent is signed; Patients with at least 2 skin lesions Exclusion criteria: Concurrent Koebner positive skin disorders; Patient receiving immunosuppressant drugs; Fitzpatrick Skin photo type V and VI; Patients under 5 years old; lesions on the face; lesions larger than 4cm in diameter; Patients with underlying liver or kidney disease

##### Intervention groups

Patients of 5-60 years old with multiple smear positive cutaneous leishmaniasis lesions who referred to the treatment center were selected. The method of intervention is 1550nm fractional laser with resurfacing parameter of 40 mJ per MTZ (microthermal zone) weekly for up to 6 weeks plus Sina-Ampholish ointment twice daily on the lesion surface. In each patient one typical lesion does not get treatment as control group

##### Main outcome variables

Healing of wounds and elimination of induration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141123020052N3**

Registration date: **2020-08-06, 1399/05/16**

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

Last update: **2020-08-06, 1399/05/16**

Update count: **0**

##### Registration date

2020-08-06, 1399/05/16

##### Registrant information

##### Name

Ahmad Reza Parhizkar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5331 6300

##### Email address

parhizkara@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2021-03-21, 1400/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of combination of fractional 1550nm laser therapy plus Sina-ampholeish ointment on cutaneous leishmaniasis

#### Public title

Efficacy of combinig fractional 1550nm laser and topical Sina-ampholish in old world cutaneous leishnaniasis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Less than 1months of the disease duration Written informed consent. at least 2 skin lesions present

##### Exclusion criteria:

Concurrent Koebner positive skin disorders patient who treating under immunodeficient drugs Skin phototype FitzPatrick V and VI patient below 5 years old lesions on the face lesions of more than 4 centimeter diameter patients who have underlying liver or kidney disease

#### Age

From **5 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **65**

More than 1 sample in each individual

Number of samples in each individual: **2**

An indurated painless purple plaque or nodule with or without central ulceration

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University Kazerun branch

##### Street address

Central office of Islamic Azad University., North Ghaani Ave., Shiraz Town,

##### City

Kazerun

#### Province

Fars

#### Postal code

7139777669

#### Approval date

2019-10-01, 1398/07/09

#### Ethics committee reference number

IR.IAU.KAU.REC.1398.106

### 2

#### Ethics committee

##### Name of ethics committee

Ethics committee of Fasa University of Medical Sciences

##### Street address

Fasa University of Medical Sciences, Ebn-Sina Square

##### City

Fasa

##### Province

Fars

##### Postal code

۷۴۶۱۶۸۶۶۸۸

#### Approval date

2020-07-14, 1399/04/24

#### Ethics committee reference number

IR.FUMS.REC.1399.070

## Health conditions studied

### 1

#### Description of health condition studied

Skin lesions caused by cutaneous leishmaniasis

#### ICD-10 code

B55.1

#### ICD-10 code description

Cutaneous leishmaniasis treatment laser

## Primary outcomes

### 1

#### Description

Induration of the lesion

#### Timepoint

Before intervention and 1, 2, 3, 4, 5, 6 weeks after intervention and 4 weeks after the end of treatment.

#### Method of measurement

The degree of stiffness in touch by the researcher

### 2

#### Description

Ulcer diameter

#### Timepoint

Before intervention and 1, 2, 3, 4, 5, 6 weeks after intervention and 4 weeks after the end of treatment.

#### Method of measurement

By the ruler

### 3

#### **Description**

Lesion diameter

#### **Timepoint**

Before intervention and 1, 2, 3, 4, 5, 6 weeks after intervention and 4 weeks after the end of treatment.

#### **Method of measurement**

By the ruler

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: Selected skin lesions are treated in 6 pass with fractional laser of 1550nm wave length with 40mj energy in each MTZ weekly for 6 weeks. Sina-Ampholish cream used twice daily during the treatment

#### **Category**

Treatment - Devices

#### 2

#### **Description**

Control group: one lesion with average diameter of all skin lesions is selected as control and no treatment is given.

#### **Category**

Treatment - Devices

### **Recruitment centers**

#### 1

#### **Recruitment center**

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

Dermatology office of Dr.Parhizkar

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

Ahmad Reza Parhizkar

##### **Street address**

Pezeshkan clinic, Hafez street

##### **City**

Fasa

##### **Province**

Fars

##### **Postal code**

7461917949

##### **Phone**

+98 71 5335 5222

##### **Email**

ahmadrparhizkar@yahoo.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

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

Islamic Azad University

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

Mohammad Hossien Marhamatizadeh

#### **Street address**

Central office of Islamic Azad University., North Ghaani Ave., Shiraz Town,

#### **City**

Kazerun

#### **Province**

Fars

#### **Postal code**

7139777669

#### **Phone**

+98 71 4223 9933

#### **Fax**

#### **Email**

Drmarhamati@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

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

No

#### **Title of funding source**

Dr. Ahmadreza Parhizkar

#### **Proportion provided by this source**

50

#### **Public or private sector**

Private

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Persons

#### 2

#### **Sponsor**

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

Fasa University of Medical Sciences

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

Dr. Mojtaba Frajam

#### **Street address**

Vice Chancellor of Research, Fasa University of Medical Sciences, Ebn-Sina Square

#### **City**

Fasa

#### **Province**

Fars

#### **Postal code**

7461686688

#### **Phone**

+98 71 5331 6300

#### **Email**

research@fums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

No

#### **Title of funding source**

Dr. Ahmadreza Parhizkar  
**Proportion provided by this source**  
50  
**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Persons

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Islamic azad university of kazerun  
**Full name of responsible person**  
Ahmadreza parhizkar  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Level 3, Hafez street, next to Mellat Bank, Fasa, Fars province, Iran,  
**City**  
Fasa  
**Province**  
Fars  
**Postal code**  
7461917949  
**Phone**  
+98 71 5335 5222  
**Email**  
ahmadrparhizkar@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic azad university of kazerun  
**Full name of responsible person**  
Ahmadreza parhizkar  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Level 3, Hafez street, next to Mellat Bank, Fasa, Fars

province, Iran,  
**City**  
Fasa  
**Province**  
Fars  
**Postal code**  
7461917949  
**Phone**  
+98 71 5335 5222  
**Email**  
ahmadrparhizkar@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic azad university of kazerun  
**Full name of responsible person**  
Ahmadreza parhizkar  
**Position**  
Assistant professor  
**Latest degree**  
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**Email**  
ahmadrparhizkar@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no further information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available