

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

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

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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
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Person responsible for updating data

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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