

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of fractional CO2 laser efficacy in treatment of atrophic scar of cutaneous leishmaniasis

Protocol summary

Summary

Aims: The aim of present study is evaluation of the efficacy of fractional CO2 laser in treatment of atrophic scar of cutaneous leishmaniasis. Inclusion and Exclusion criteria: All patients more than 12 years old with atrophic scar of cutaneous leishmaniasis in hand or face are entered to study with informed satisfaction. Patients with chronic diseases like diabetes, immunodeficiency patients and individuals with skin type VI are excluded the study. Study intervention: First the location is cleaned by isopropyl alcohol 70%, then dressing is performed for local anesthesia. After 45 minutes, the location is washed and dried. The affected site will be treated without overlap by beam size 120 micron and pals energy between 50-90 mj and densitometry between 50-100 spot/cm2. Pals energy rate will base on kind of skin and scar severity. Any cooling device will not be performed during treatment. Ice Pack is used after treatment for sedating pain and irritation. All patients will be used sunscreen cream during and after treatment. For each patient, three treatment sessions spaced one month will used. Primary outcomes: Evaluation of patients is in start of therapy, during therapy sessions, and 3 and 6 months after the last treatment session. Evaluation will be determined by the digital photography in suitable angle and distance by determined light and camera and also based on patient satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404303862N12**
Registration date: **2014-07-03, 1393/04/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-03, 1393/04/12

Registrant information

Name

Farahzad Jababri Azad

Name of organization / entity

Mashahd University of Medical Scineces

Country

Iran (Islamic Republic of)

Phone

+98 51 1843 6626

Email address

banihashemim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of fractional CO2 laser efficacy in treatment of atrophic scar of cutaneous leishmaniasis

Public title

Evaluation of laser efficacy in treatment of cutaneous leishmaniasis lesion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age more than 12 years old; informed

consent of patient for participating in study; atrophic scar in hand or face with duration of improvement more than one year Exclusion criteria: patients with chronic disease like diabetes and collagen vascular diseases that have a problem in scar healing; hypertrophic or keloid scars; history for receiving isotretinoin during last year; pregnancy or breastfeeding; immunodeficiency patients like patients under immunosuppressive medicines; patients who don't complete treatment period or don't refer for follow ups; skin type VI; history of radiotherapy in laser locations; patients with positive coiner disease like psoriasis and vitiligo

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

901024

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 healing

Timepoint

For the first before intervention, then during therapy sessions, and 3 and 6 months after the last treatment session

Method of measurement

Measuring the size of induration and scar

Secondary outcomes**1****Description**

Side effects including erythema, edema, petechiae, discoloration and scar

Timepoint

start of therapy, 3 and 6 months after the last treatment session

Method of measurement

Physical exam

Intervention groups**1****Description**

Cleansing of location by isopropyl alcohol 70%, and then dressing is performed for local anesthesia. After 45 minutes, the location is washed and dried. Treatment will be performed with laser beam size 120 micron and pulse energy between 50-90 mj and densitometry between 50-100 spot/cm² in three sessions of treatment with duration of one month.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Cutaneous leishmaniasis Research Center, Ghaem Hospital

Full name of responsible person

Dr Mahnaz Banihashemi

Street address

Ghaem hospital, Ahmad Abad street

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences, Vice
Chancellor for Research
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical
Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences, Vice Chancellor
for Research

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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Hamid Reza Moghimi
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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
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Person responsible for updating data

Contact

Name of organization / entity
Leishmaniasis Research Center
Full name of responsible person
Akram Momenzadeh
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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