Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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, dispigmentation 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 pals 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
Position
Dermatology Resident
Other areas of specialty/work
Street address
Ghaem Hospital, Ahmad Abad Street
City
Mashhad
Postal code
Phone
+98 51 1841 0135
Fax
Email
src@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mahnaz banihashemi
Position
Associate professor of Dermatology
Other areas of specialty/work
Street address
Cutaneous Leishmaniasis Research center, Ghaem hospital, Ahmad Abad Street
City
Mashhad
Postal code
Phone
+98 51 1801 2851
Fax
Email
banihashemim@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Leishmaniasis Research Center
Full name of responsible person
Akram Momenzadeh
Position
Reserach Assistant
Other areas of specialty/work
Street address
Ghaem Hospital, Ahmad Abad Street
City
Mashhad
Postal code
Phone
+98 51 1841 0135
Fax
Email
src@mums.ac.ir
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