

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy of PDL laser via 532 nm laser in treatment of solar lentigo

Protocol summary

Summary

Objectives: The purpose of this study is comparison efficacy of PDL laser with 532 nm laser in treatment of solar lentigo. Design: This study will be conducted in 20 patients with facial or hand lentigines that will be admitted to Emam Khomeini hospital. Inclusion criteria: patients with at least two solar lentigo; Skin type 2-4. Exclusion criteria: History of photo therapy; History of scar formation; History of any treatment of lentigo, vitiligo, psoriasis. Intervention: The patients will randomly be allocated into two groups. Group I: Patients will receive PDL laser one to three times with seven joules per cubic centimeter energy during five to ten minutes. Group II: Patients will receive 532 nm laser one to three times with five joules per cubic centimeter energy during five to ten minutes. Main outcome measures: Pigmentation Grade Before and one month after the intervention will be measured according to degree of reducing pigmentation: poor; medium; excellent. Also the pain is measured in the time of intervention with Visual Analogue Scale.

General information

Acronym

Effect of PDL laser in treatment of lentigo

IRCT registration information

IRCT registration number: **IRCT2016123131671N1**

Registration date: **2017-04-28, 1396/02/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-28, 1396/02/08

Registrant information

Name

Arezou Bagherzadeh

Name of organization / entity

Ahvaz jondishapur university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 8068

Email address

bagherzadeh.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

Expected recruitment start date

2017-08-30, 1396/06/08

Expected recruitment end date

2018-03-30, 1397/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of PDL laser via 532 nm laser in treatment of solar lentigo

Public title

Treatment of solar lentigo with PDL laser

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients with at least two solar lentigo; Skin type 2-4; Having greater than 15 years old. Exclusion criteria: Pregnancy; History of photo therapy; History of scar formation; History of any treatment of lentigo, vitiligo, psoriasis; UN real expectation of laser treatment.

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic Committee of Ahvaz Jundishapur University of
Medical Sciences

Street address

No 3, University street, Golestan Blvd, Ahvaz

City

Ahvaz

Postal code**Approval date**

2014-06-16, 1393/03/26

Ethics committee reference number

ajums.REC.1393.422

Health conditions studied**1****Description of health condition studied**

Skin lesions of lentigo

ICD-10 code

L81.4

ICD-10 code description

Melanin Hyperpigmentation

Primary outcomes**1****Description**

Pigmentation Grade

Timepoint

Before and one month after the intervention

Method of measurement

By reducing pigmentation: poor; medium; excellent

2**Description**

Pain

Timepoint

In the time of intervention

Method of measurement

Visual Analogue Scale

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

Scar formation

Timepoint

A month after the intervention

Method of measurement

Observational

2**Description**

Hyper-pigmentation and hypopigmentation after
inflammation

Timepoint

A month after the intervention

Method of measurement

Observational

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

Laser Type: PDL The amount of energy: Seven joules per
cubic centimeter Laser spot size: Five Millimeter
Frequency of use: One to three times. Duration: Five to
ten minutes Country: United States

Category

Treatment - Other

2**Description**

Laser Type: Nd:YAG Laser(Neodymium-doped Yttrium
Aluminium Garnet) The amount of energy: Five joules per
cubic centimeter Laser spot size: Three Millimeter
Frequency of use: One to three times Duration: Five to
ten minutes Country: United States

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Seyed Mohammad Radmanesh

Street address

No. 4, Ave. 1, Kianpars Blvd.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz University of Medical Sciences

Full name of responsible person

Seyed Mohammad Radmanesh

Street address

No. 5, Ave. 4, Kianpars Blvd.

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, Ahvaz 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

Arezou Bagherzadeh

Position

Resident of Dermatology

Other areas of specialty/work

Street address

No. 12, Enghelab Chamber, Golestan

City

Ahvaz

Postal code

Phone

+98 61 3222 3582

Fax

+98 61 3338 1110

Email

dr.arezoubagherzadeh@gmail.com;

bagherzadeh.a@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Seyed Mohammad Radmanesh

Position

Dermatologist

Other areas of specialty/work

Street address

No. 12, Enghelab Chamber, Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 61 3292 1837

Fax

Email

radmanesh33@gmail.com;

mostafafatahi777@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Arezou Bagherzadeh

Position

Resident of Dermatology

Other areas of specialty/work

Street address

No. 12, Enghelab Chamber, Golestan blvd

City

Ahvaz

Postal code

Phone

+98 61 3222 8532

Fax

Email

dr.arezoubagherzadeh@gmail.com;

bagherzadeh.a@ajums.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