Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating Acne-Erythema Improvement following Long-Pulsed 595nm Pulsed-Dye Laser

Protocol summary

Study aim
Determining the therapeutic effect of PDL laser in the treatment of acne erythema sufferers

Design
Clinical trial on 28 patients in the form of intervention on one side of the patient's face and the control on the other side of the face in a parallel randomized and unblinded manner. Simple randomization method using rand function of Excel software was used for randomization.

Settings and conduct
Patients with acne erythema referred to Razi Skin Hospital in Tehran will undergo two sessions of PDL laser treatment on one side of the face with low energy (8-9 J/cm2) and pulse duration of 3 msec with a time interval of 4 weeks. During the study, high-quality photos will be taken of each patient before the start of laser treatment, in the fourth week, in the eighth week and in the third month, and the effectiveness of the laser will be compared with the other side of the face.

Participants/Inclusion and exclusion criteria
Entry requirements: The patient has moderate to severe acne Definitive diagnosis of acne erythema in a patient in 3-4 months of treatment with isotretinoin Age between 14 and 36 years Non-entry conditions: pregnancy Use of fillers by the patient in the past 3 months Failure of the patient to participate in the study at the beginning or during the study

Intervention groups
Patients with acne erythema will undergo two sessions of PDL laser treatment with a time interval of 4 weeks on one side of the face, and during the study, each patient will be photographed four times and the effectiveness of the laser will be compared with the other side of the face.

Main outcome variables
Acne severity Acne erythema grade The number of acne erythema Acne scars

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230202057307N1**
Registration date: **2023-11-06, 1402/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-06, 1402/08/15**
Update count: **0**

Registration date
2023-11-06, 1402/08/15

Registrant information
Name
Saina Mobarhan
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 914 264 2448
Email address
sainamobarhan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-06-19, 1403/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluating Acne-Erythema Improvement following Long-Pulsed 595nm Pulsed-Dye Laser

Public title
effect of pulsed dye laser in treatment of acne
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
moderate to severe acne Definite diagnosis of acne erythema Taking isotretinoin for at least three months
Exclusion criteria:
pregnancy Use of face filler in the last three months
Age
From **14 years** old to **36 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **28**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Razi Hospital,Vahdat Islamic Square
City
Tehran
Province
Tehran
Postal code
1199663911
Approval date
2023-01-01, 1401/10/11
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.627

Health conditions studied

1

Description of health condition studied
Acne
ICD-10 code
L70
ICD-10 code description
Acne

Primary outcomes

1

Description
The number of acne erythema
Timepoint
Measuring the number of acne erythema at the beginning of the study, four, eight and twelve weeks after the start of the laser
Method of measurement
checklist

2

Description
Grading of acne erythema
Timepoint
Measurement the grading of acne erythema at the beginning of the study, four, eight and twelve weeks after the start of the laser
Method of measurement
checklist

3

Description
acne scars
Timepoint
Measurement of acne scars at the beginning of the study, four, eight and twelve weeks after the start of the laser
Method of measurement
checklist

4

Description
severity of acne
Timepoint
Measuring the severity of acne at the beginning of the study, four, eight and twelve weeks after the start of the laser
Method of measurement
checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: PDL laser on one side of the face
Category
Treatment - Other

2

Description
Control group: The other side of the face without laser
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Razi Hospital
Full name of responsible person
saina mobarhan
Street address
Razi hospital, vahdat eslami Square
City
tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5563 0553
Email
razihospital@sina.tums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
saina mobarhan
Street address
razi hospital, vahdat eslami square
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Tehran
Postal code
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Phone
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Email
razihospital@sina.yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
1
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
saina mobarhan
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
dermatology
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Position
professor
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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

saina mobarhan

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

dermatology

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable