

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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/cm<sup>2</sup>) 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1199663911

#### Phone

+98 21 5563 0553

#### 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

#### Street address

Razi hospital,vahdat eslami square

#### City

tehran

#### Province

Tehran

#### Postal code

1199663911

#### Phone

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#### Email

sainamobarhan@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Amir hoshang Ehsani

#### Position

professor

#### Latest degree

Specialist

#### Other areas of specialty/work

dermatology

#### Street address

Razi hospital, vahdat eslami square

#### City

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#### Province

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**Phone**  
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**Email**  
saniamobarhan@gmail.com

## 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  
**Street address**  
Razi hospital,vahdat eslami square  
**City**  
tehran  
**Province**  
Tehran  
**Postal code**

## 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