

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the efficacy and safety of PDL, IPL and Q switch Nd:YAG 1064 laser in the treatment of mild to moderate inflammatory acne vulgaris

Protocol summary

Study aim

Comparison of the efficacy and safety of PDL, IPL and long pulse Nd:Yag 1064 laser in the treatment of mild to moderate inflammatory acne vulgaris

Design

A three-arm , parallel-group, without control group, single-blind, randomized, phase 2 clinical trial on 36 patients.

Settings and conduct

The diagnosis is made in the dermatology clinic of Rasool Akram Hospital. Then, the eligible patients are randomly divided into three groups for laser treatment through the selection of non-transparent envelopes, in order to blind the patients to the choice of treatment modality. The first group is treated with a PDL laser with a wavelength of 585 nm, a spot diameter of 7 mm, a fluence of 3 J, and a pulse duration of 350 microseconds. In the second group, patients under treatment with IPL laser with a wavelength of 240-1200 nm and a fluence of 7 J, and in the third group of patients under treatment with a Nd:Yag long pulse laser with a wavelength of 1064 nm and a pulse duration of 40 microseconds and with a fluence of 40 J. Patients are treated with laser in 3 sessions at an interval of 2 weeks in the dermatology clinic of Hazrat Fatemeh Hospital.

Participants/Inclusion and exclusion criteria

Participants over 18 years old with mild to moderate facial inflammatory acne Not taking isotretinoin in the last 6 months. Patient satisfaction No history of hypertrophic scar or keloid Not taking anticoagulant drug in the last 2 months No Pregnancy or breastfeeding No history of Photosensitivity and rheumatologic diseases

Intervention groups

The study does not have a control group. In the first group of patients, three sessions of PDL laser will be treated. In the second group, three sessions of IPL laser will be treated, and in the third group of patients, three

sessions of Nd:YAG laser will be treated.

Main outcome variables

Severity of acne lesions, The number of acne lesions, Quality of life

General information

Reason for update

Due to the lack of long pulse mode on the Nd:YAG device available at the laser center, another mode of the same wavelength, the Q-switch form, has been used.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150529022468N6**

Registration date: **2023-08-12, 1402/05/21**

Registration timing: **prospective**

Last update: **2025-12-17, 1404/09/26**

Update count: **1**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

Mohammadreza Ghassemi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10
Expected recruitment end date
2024-10-01, 1403/07/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy and safety of PDL, IPL and Q switch Nd:YAG 1064 laser in the treatment of mild to moderate inflammatory acne vulgaris

Public title
Comparison of the efficacy and safety of PDL, IPL and long pulse Nd:Yag 1064 laser in the treatment of mild to moderate inflammatory acne vulgaris

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Participants over 18 years old with mild to moderate facial inflammatory acne Not taking isotretinoin in the last 6 months.
Exclusion criteria:
History of hypertrophic scar or keloid Anticoagulant drug consumption in the last 2 months Pregnancy or breastfeeding Photosensitivity and rheumatologic diseases Dissatisfaction of patients

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Over time, patients are randomly divided into three groups. The method of randomization is *Random allocation rule*. A representative of the first, second and third groups is written and placed inside envelopes and in order to perform a random sequence (allocation concealment) on the participants, the table of random numbers will be used.

Blinding (investigator's opinion)
Single blinded

Blinding description
A representative of the first, second, and third groups is written and placed inside opaque envelopes (which cannot be seen inside the envelope). Participant are blinded to the intervention until the end of the study.

Placebo
Not used

Assignment

Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran university of medical sciences, Central headquarters building, Research and technology vice-chancellor, next to Milad tower, Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-04-18, 1402/01/29

Ethics committee reference number

IR.IUMS.FMD.REC.1402.036

Health conditions studied

1

Description of health condition studied

Infammatory facial Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Leeds revised acne grading system

Timepoint

Checking the severity of acne at the beginning of the study and on days 14, 28 and 42 after the intervention

Method of measurement

Based on the number of lesion in the photo and comparing with "Leeds revised acne grading system" a score of 1-12 is given

Secondary outcomes

1

Description

Severity of inflammatory facial acne

Timepoint

Measuring the criteria of the global acne grading system at the beginning of the study and on the 14th, 28th, and 42nd days after the start of the study

Method of measurement

Based on the type of lesions, from comedone type to papule, pustule and nodulocystic acne, a score is given from 1 to 44

2

Description

Quality of life index

Timepoint

Beginning and end of the study (0 and 42th days)

Method of measurement

"Dermatology Life Quality Index " questionnaire

Intervention groups

1

Description

Intervention group 1: Patients in the first group were treated 3 times with an interval of two weeks with PDL laser with a wavelength of 585 nanometers, laser spot diameter of 7 mm, fluence of 3 joules, and pulse duration of 350 microseconds

Category

Treatment - Devices

2

Description

Intervention group 2: In the second group, patients are treated 3 times with an interval of two weeks with IPL laser with a wavelength of 240-1200 nanometers and fluence of 7 joules.

Category

Treatment - Devices

3

Description

Intervention group 3: In the third group, patients are treated 3 times with an interval of two weeks with Nd: Yag long pulse laser with a wavelength of 1064 nanometers and a fluence of 40 joules and a pulse duration of 40 microseconds.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul akram hospital

Full name of responsible person

Mohammadreza Ghassemi

Street address

Rasoul akram hospital, Mansouri street, Sattarkhan Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

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

Iran University of Medical Sciences

Full name of responsible person

Mohammadreza Ghassemi

Position

Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual Data: All potentially shareable data after de-identifying individuals. Study protocol: The entire protocol can be shared after de-identifying people. Statistical analysis map: The whole map can be shared after de-identifying people. Informed Consent Form: Can be shared after de-identifying individuals. Clinical Study Report: The entire report can be shared after de-identifying individuals. Codes used in the analysis: All codes can be shared after de-identifying people. Data classification system: It can be shared after de-identifying people.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

In case of research on a similar topic, he/she can use the data of this study.

From where data/document is obtainable

1- Email: Keramatihaniyeh73@gmail.com 2- Postal address: Rasool Akram Hospital, Mansouri St., Sattarkhan Ave., Tehran

What processes are involved for a request to access data/document

After correspondence via e-mail or postal address, it is possible to receive data and documents within a period of about two months, if the researcher wishes.

Comments