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 Scienses

Country
Iran (Islamic Republic of)

Phone
+98 21 6650 2040

Email address
ghassemi.mr@iums.ac.ir

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
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2390
Email
Ghassemi.mr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
Iran university of medical science, Next to Milad tower, Hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2703
Email
falak.r@iums.ac.ir
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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Rasoul Akram hospital, Mansouri street, Sattarkhan Ave

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Person responsible for scientific inquiries

Contact

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Iran University of Medical Sciences

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+98 21 6435 2390

Email
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Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammadreza Ghassemi

Position
Associate professor

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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., Sattar Khan 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