

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Efficacy, safety, satisfaction, tolerability and treatment durability of long-pulsed Nd:YAG 1064 nm laser compared with fractional Q-switch Nd:YAG 1064 nm laser in the treatment of active acne vulgaris in patients under treatment with azithromycine: An assessor-analyst-blinded split-body triple-arms randomized controlled clinical trial

Protocol summary

Study aim

Determining of effectiveness of fractional Q switch laser compared with Nd:YAG laser in the treatment of active acne of face

Design

Clinical trial with control group, Single-blind , randomized on 20 patients, simple randomization was used for randomization

Settings and conduct

In all patients who entered the study with active acne, before the start of the study, using Canon EOS 750D digital photography camera with the same distance and high quality, the desired images of the patients will be prepared. Each patient is treated with laser for three sessions with an interval of 3 weeks, and evaluation is done at each visit and 4 weeks after the last laser session. Evaluation of the study results by an evaluator blinded to the type of intervention and based on the images prepared by Waste will be done in each meeting.

Participants/Inclusion and exclusion criteria

The criteria for entering the study are according to the following: 1. Patients 15 to 50 years old 2. Patients with a confirmed diagnosis of active facial acne 3. The patient has not received any treatment for his illness in the past three months. 4. Lack of serious underlying disease 5. The patient's cooperation in carrying out therapeutic interventions and referring for all therapeutic sessions

Intervention groups

The study population is patients with moderate to severe active facial acne referring to Hazrat Rasool Akram Hospital. Affected patients were examined by a dermatologist, and if there were entry criteria and no exit criteria, they were entered into the plan by the available method, and for each patient, fractional

Kioswitch laser was performed on one side of the face and Nd:YAG laser on the opposite side. will be Also, forehead or trunk acne of the patient is considered as a control group.

Main outcome variables

Effectiveness of treatment; Safety of treatment; Tolerability of treatment; Satisfaction with treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170809035597N4**
Registration date: **2023-06-10, 1402/03/20**
Registration timing: **prospective**

Last update: **2023-06-10, 1402/03/20**

Update count: **0**

Registration date

2023-06-10, 1402/03/20

Registrant information

Name

Azadeh Goodarzi

Name of organization / entity

Iran University of Medical Sciences (IUMS), Rasool Akram hospital, Department of Dermatology

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy, safety, satisfaction, tolerability and treatment durability of long-pulsed Nd:YAG 1064 nm laser compared with fractional Q-switch Nd:YAG 1064 nm laser in the treatment of active acne vulgaris in patients under treatment with azithromycin: An assessor-analyst-blinded split-body triple-arms randomized controlled clinical trial

Public title

effect of fractional Q switch laser compared with Nd:YAG laser in the treatment of active acne of face: a single-blind randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient between 15 and 50 years old Patients with a confirmed diagnosis of facial active acne During the last 3 months, the patient has not received any treatment for the disease. Lack of underlying disease The patient's cooperation in carrying out therapeutic interventions and referring for all therapeutic sessions

Exclusion criteria:

The patient has been treated for acne in the last three months The presence of a serious underlying disease in the person

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **3**

For each patient, fractional Q-switch laser is performed randomly on one side of the face and Nd:YAG laser on the opposite side. Also, forehead or trunk acne of the patient is considered as a control group.

Randomization (investigator's opinion)

Randomized

Randomization description

For each patient in a random way and using sealed envelopes A and B, on one side of the face, will be treated with fractional Q-switch laser and on the opposite side, Nd:YAG laser. The right side of the face of group A will be treated with Q-switch laser and the left side will be treated with Nd:YAG laser and vice versa. Also, the patient's forehead or trunk acne is considered as a control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluation of the results of the studies will be done by a dermatologist as a blind evaluator to the type of intervention and based on the clinical images of the patients' faces in each session. Due to the clear difference between the mentioned therapeutic interventions, it was not possible to blind the therapist and as a result, the study will be conducted in a one-sided blind manner.

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

Rasoul Akram Hospital, At the corner of Mansouri St, Niyayesh St, Satarkhan St

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2023-05-13, 1402/02/23

Ethics committee reference number

IR.IUMS.FMD.REC.1402.074

Health conditions studied

1

Description of health condition studied

Acne

ICD-10 code

Acne vulga

ICD-10 code description

L70.0

Primary outcomes

1

Description

Effectiveness of laser treatment on acne

Timepoint

Determining the severity of acne at the beginning of treatment and 4 weeks after the end of treatment

Method of measurement

Clinical evaluation by photographing with Canon EOS 750D digital photography camera in room light and also counting the number of active lesions 2. Determination of acne severity using Leeds revised acne grading system which is based on the lesions in the photo and comparing with existing criteria from 1 to 12 The severity of acne is scored. 3. Examining the severity of acne using the global acne grading system) which is based on the location of acne lesions on the face and also based on the type of lesions from comedone type to papule, pustule and nodulocystic acne with a score from 1 to 44 It is considered that grade 1 to 18 is mild, 19 to 30 is moderate, 31 to 38 is severe, and a grade equal to or greater than 39 is considered very severe.4. The degree of satisfaction of the doctor and the patient with the treatment based on the physician/patient global assessment score: (completely satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied and completely dissatisfied)The photos are reviewed and scored by a dermatologist who is blind to the study, and at the end, the study data is analyzed by a blind statistician.

2

Description

Safety of treatment

Timepoint

Examination of treatment side effects before and after each session and 4 weeks after the end of treatment

Method of measurement

Using doctor and patient questionnaires (including pain, swelling, erythema and PIH)

3

Description

Tolerability of the treatment

Timepoint

Checking the tolerability of the treatment before and after each session and 4 weeks after the end of the treatment

Method of measurement

Using a questionnaire (yes, no)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The study population is patients with moderate to severe active facial acne referring to Hazrat Rasool Akram Hospital. Affected patients were examined by a dermatologist, and if there were entry criteria and no exit criteria, they were entered into the plan by the available method, and for each patient, fractional Q-switch laser was performed on one side of the face and Nd:YAG laser on the opposite side. Randomization is done by sealed envelopes. Each patient is treated with laser for three sessions with an interval of 3 weeks. Fractional Qswitch laser settings: Pulse rate: 10 Hz, spot size: 10 mm, fluence: 1.5 j/cm² 1064 nm Nd:YAG laser settings: Pulse rate: 4 Hz, spot size: 6 mm, fluence: 60 j/cm². Evaluation is done in each laser sessions and 4 weeks after the last laser appointment.

Category

Treatment - Devices

2

Description

Control group: Acne on the forehead or trunk of the patient is considered as the control group.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

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

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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

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