Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Efficacy, safety, satisfaction, toleberility and treatment duribility 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
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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, toleberility and treatment duribility 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

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 treated with fractional Q-switch laser and on the opposite side, Nd:YAG laser. The right side of the face of group A will treaated with Q-switch laser and the left side will 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

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Tehran

Province
Tehran

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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
Checkiing 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
Dorian Maghsoodloo
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Sponsors / Funding sources

1

Sponsor
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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
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Full name of responsible person
Azadeh goodarzi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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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