Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The efficacy of adjuvant Nd-Yag laser in the long-term treatment of moderate inflammatory acne and its effect on acne induced erythema and scar

Protocol summary

Study aim

Assessing the effect of Nd-YAG laser on moderate acne and its effect of acne induced eryhtema and scar

Design

Clinical trial with a control group, with parallel groups, without blindness, randomized, phase 2 on 21patients. The SealedEnvelope website would be used for randomization.

Settings and conduct

This research will be done in the laser department of Razi Hospital. Nd-YAG laser will be applied on one side of the patient's face every 2 weeks for 4 times. Considering that blinding is not possible, the only blind person in this study would be the analyst.

Participants/Inclusion and exclusion criteria

Inclusion: Aged 18-60 Clinical diagnosis of moderate acne by a dermatologist Non inclusion: Pregnancy or breastfeeding during the intervention. History of internal diseases, including endocrine diseases causing acne. Alteration in diet and lifestyle during the study. Having consumed systemic therapy for acne in the last 4 weeks. Having consumed oral antibiotics in the last 3 months Having consumed topical therapy for acne in the last 2 weeks. Having consumed isotretinoin, undertaken laser, and peeling in the last 6 months. Photosensitivity. Severe or nodularis acne. Polycystic ovary syndrome

Intervention groups

The first intervention group: one side of the patient's face receiving Nd-YAG laser. And the second intervention group (control): the other side of the patient's face that does not receive laser.

Main outcome variables

Acne severity; Patients' satisfaction with acne recovery; Laser complications; patient pain during laser therapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181005041243N3**
Registration date: **2022-10-15, 1401/07/23**
Registration timing: **prospective**

Last update: **2022-10-15, 1401/07/23**
Update count: **0**

Registration date

2022-10-15, 1401/07/23

Registrant information

Name
Nika Kianfar
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The efficacy of adjuvant Nd-Yag laser in the long-term treatment of moderate inflammatory acne and its effect on acne induced erythema and scar

Public title
Efficacy of adjuvant Nd-Yag in acne

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged 18-60 Clinical diagnosis of moderate acne by a dermatologist

Exclusion criteria:
Pregnancy or breastfeeding during the intervention history of internal diseases, including endocrine diseases causing acne Alteration in diet and lifestyle during the study Having consumed systemic therapy for acne in the last 4 weeks Having consumed oral antibiotics in the last 3 months Having consumed topical therapy for acne in the last 2 weeks Having consumed isotretinoin, undertaken laser, and peeling in the last 6 months Photosensitivity Severe or nodularis acne Polycystic ovary syndrome

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **21**
More than 1 sample in each individual
Number of samples in each individual: **2**
Of side of the face, based on randomization, would receive laser therapy, while the other side would not receive laser therapy

Randomization (investigator's opinion)
Randomized

Randomization description
Individual blocks will be created without stratified randomization by statistical software. And another person (rather than the doctor-researcher-patient) would do the randomization. For this, blocks of size 6 were selected for 2 treatment groups (one side of the face receiving laser treatment and the other side without treatment as a control group) so that the total sample size is 24. Accordingly, patients will receive each treatment based on the randomized sequence.

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
Vahdate eslami St. - Razi alley. Razi Dermatology Hospital

City
Tehran

Province
Tehran

Postal code
119963911

Approval date
2021-06-27, 1400/04/06

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.346

Health conditions studied

1

Description of health condition studied
Acne

ICD-10 code
L70

ICD-10 code description
Acne

Primary outcomes

1

Description
Acne severity

Timepoint
At the first session and then 2 and 5 months after that

Method of measurement
Acne severity will be assessed based on Hayashi acne grading/ based on the observations of two dermatologists assessing the before and after photographs

2

Description
Acne scarring

Timepoint
At the first session and then 2 and 5 months after that based on the size of the scarring in millimeters

Method of measurement
Acne scarring will be assessed based on The Goodman quantitative postacne scarring grading system / based on the observations of two dermatologists assessing the

before and after photographs

3

Description
Pain scoring during laser
Timepoint
At each treatment session (4 times)
Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
The side effects of laser therapy, including erythema, edema, and blisters
Timepoint
It would be evaluated after each treatment session.
Method of measurement
Dermatologist's visit and patients statements

Intervention groups

1

Description
Intervention group: Nd-YAG laser is treated on one side of the patient's face with setting and PD=25 ms and SS=4 mm. The treatment session would be 4 times every two weeks.
Category
Treatment - Devices

2

Description
Control group: The other side of the face would receive no laser therapy.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Masoud Habibi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran 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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Nika Kianfar
Position
Post doc researcher
Latest degree
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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
Undecided - It is not yet known if there will be 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
The data file information of the participants - study protocol - statistical analysis plan - informed consent form will be published after de-identification.
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
Receiving data will be available for researchers working in academic and scientific institutions or people who are also engaged in industry
Under which criteria data/document could be used
In order to conduct scientific studies
From where data/document is obtainable
Dr. Nika Kianfar nika_kianfar@yahoo.com
What processes are involved for a request to access data/document
After sending the request by providing a logical reason, the data will be sent to the person within 2 weeks.
Comments