

# 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 erythema and scar

##### Design

Clinical trial with a control group, with parallel groups, without blindness, randomized, phase 2 on 21 patients. 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2285 7201

##### Email address

N-kianfar@alumnus.tums.ac.ir

##### 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

##### **Street address**

Vahdate eslami St. Razi alley

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1199663911

##### **Phone**

+98 912 475 9738

#### **Email**

masoud.habiby1181342@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Maryam Nasimi

##### **Street address**

Vahdate eslami- Razi alley- Razi Dermatology Hospital

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1199663911

##### **Phone**

+98 21 5563 0553

##### **Email**

nsm.maryam@gmail.com

#### **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**

Medical doctor

##### **Other areas of specialty/work**

General Practitioner

##### **Street address**

No.1, afshar alley, daavi alley, pasdaran ave.

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##### **Province**

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n-kianfar@alumnus.tums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Maryam Nasimi  
**Position**  
Associate Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Nika Kianfar  
**Position**  
Post doc researcher  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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n-kianfar@alumnus.tums.ac.ir

## 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