

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the efficacy and side effects of fractional Q-Switched ND:YAG laser in the treatment of ophthalmia in patients

Protocol summary

Study aim

Determination of the efficacy and side effects of QS Nd-yag laser in the treatment of dark circles

Design

A clinical trial in phase 2, without control group and with an intervention group, comparable before and after, not blind, on 37 volunteers for treatment dark circles around the eyes.

Settings and conduct

This project is performed in the clinic of Skin and Stem Cell Research Center of Tehran University Medical Sciences and in the treatment of dark circles volunteers. Patients, if there are conditions for admission to the study, enter the study after obtaining written consent and are treated in the dark area around the eye by fractional QS Nd-yag laser. Each patient received 6 treatment sessions with 2 weeks interval (a total of 3 months of treatment). Also, the thickness and elasticity of the skin and the amount of pigment around the eyes are checked with a skin ultrasound device and cotometer and maxameter, before and one month after the end of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-65 years old; the cause of darkness, structural and reducing fat in this area is not. Exclusion criteria: pregnancy or breastfeeding; active infection in face; history of cancer.

Intervention groups

Intervention group: the circular darkness is treated with QS Nd-yag laser

Main outcome variables

Melanin Index; side effects; patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001159N31**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-10, 1399/10/21**

Update count: **0**

Registration date

2021-01-10, 1399/10/21

Registrant information

Name

Mohamad Ali Nilforoushzadeh

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 5158

Email address

sdIrc@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and side effects of fractional Q-Switched ND:YAG laser in the treatment of ophthalmia in patients

Public title

Evaluation of the effectiveness of Q-Switched ND:YAG laser in the treatment of facial skin lesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The cause of darkness, structural and reducing fat in this area is not Age between 18 and 65 years old

Exclusion criteria:

Active infection in the face Pregnancy and breastfeeding
History of cancer

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **37**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Tehran University of Medical Sciences, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2015-09-29, 1394/07/07

Ethics committee reference number

IR.TUMS.REC.1394.854

Health conditions studied

1

Description of health condition studied

Eye dark circles

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Preorbital hyperpigmentation

Timepoint

Session 0, 4 and 6 during treatment and 3 months after treatment

Method of measurement

Intensity of the darkening of the skin around the eyes compared to other areas of the face with Mexameter device.

2

Description

Satisfaction amount

Timepoint

After completion of treatment

Method of measurement

Comparison of reduction preorbital hyper pigmentation by patient , before and after treatment According to schedule (score 0 to 10)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receive 6 fractions of treatment with 2 weeks interval (3 months in total) by QS Nd-yag laser. At each turn is done, two passes of 1000 joules on the peri-orbital areas.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

Shiva Alavi

Street address

No 4, Maryam Alley, South Kamraniyeh Street,
Tehran, Iran

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1937957511

Phone

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Shiva.alavi@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Abbas Ali Karimi

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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

50

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**

Skin and Stem cell Research Center of Tehran
University of Medical Sciences

Full name of responsible person

Shiva Alavi

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Skin and Stem cell Research Center of Tehran
University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

A Level or less

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact**Name of organization / entity**

Skin and Stem cell Research Center of Tehran
University of Medical Sciences

Full name of responsible person

Mona Mahmoudbeyk

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Developmental Biology

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable