

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Assessing the effectiveness of carboxy therapy in comparison with fractional Q-Switched ND:YAG laser for the treatment of periorbital dark circles

Protocol summary

Study aim

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

Design

The aim of this study is to evaluate the efficacy and side effects of QS Nd-yag laser in comparison with carboxy therapy in the treatment of dark circles. Twenty-eight patients with dark circles are randomly assigned to blocked randomization and are divided into two groups: carboxy-therapy, or Nd-yag switch-over treatment group.

Settings and conduct

Patients with eye dark circles that are referred to the skin and stem cell research center enter into two groups of carboxytherapy and laser intervention. In the carboxytherapy group after local anesthesia, injection is done intradermally every week, the total volume of injection in each side is one or two milliliters. The treatment sessions are held every six weeks for six sessions. The laser treatment group will receive three to four sessions of QS Nd-yag laser treatment with a certain frequency, one-month intervals. Patients are evaluated at baseline, at the end of treatment, and 3 months later. The pigmentation changes are evaluated by the Mexameter, and the brightness of the skin is measured with a calorimeter. Photographs are taken with visioface and photos of sessions 0, 4 and 6 are reviewed by two blind dermatologists. Patient satisfaction and side effects are analyzed and compared.

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

First intervention group: the circular darkness is treated with QS Nd-yag laser. Second intervention group: the

dark circles of the eye are treated with carboxytherapy.

Main outcome variables

Melanin Index; side effects; patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001159N24**

Registration date: **2019-07-31, 1398/05/09**

Registration timing: **retrospective**

Last update: **2019-07-31, 1398/05/09**

Update count: **0**

Registration date

2019-07-31, 1398/05/09

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)

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+98 21 2220 5158

Email address

sdIrc@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of carboxy therapy in comparison with fractional Q-Switched ND:YAG laser for the treatment of periorbital dark circles

Public title

Carboxy therapeutic effectiveness in comparison with fractional Q-Switched ND:YAG laser for the treatment of periorbital dark circles

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: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method (n=4)

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

Tehran University of Medical Sciences, Keshavarz

blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.TUMS.VCR.REC.1397.607

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**

The first Intervention group: the darkness around the eyes treated with QS Nd-yag laser, 4 sessions with one-month interval.

Category

Treatment - Other

2

Description

Second intervention group: Round-eye darkness Six sessions with a one-week interval are treated with carboxytherapy.

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

Nahid Nickhah

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

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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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Tehran University of Medical Sciences, Keshavarz blvd.

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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

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

Full name of responsible person

Nahid Nickhah

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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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

Specialist

Other areas of specialty/work

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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

Reproductive 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 FormUndecided - 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