

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of simultaneous effect of CO2 laser and QS laser with PRP on periorbital dark circles

Protocol summary

Study aim

Evaluation of the simultaneous effect of CO2 laser and QS laser with PRP on periorbital dark circles

Design

Clinical trial with one control group and one intervention group, with parallel groups, single-blind, Non-random assignment to intervention and control groups, phase 1-2 on 40 patients with periorbital dark circles

Settings and conduct

The intervention site is Skin and Stem Cell Research Center of Tehran University of Medical Sciences. For intervention group, patients are treated with QS lasers, fractional CO2 and PRP injections, and for control group, patients are treated only with QS lasers. In this study, blinding process will be performed and the data analyzer will be unaware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-65 years; patients with periorbital dark circles. Exclusion criteria: Active infection on face, pregnancy, Breastfeeding, history of cancer, structural darkening or loss of fat around the eyes

Intervention groups

Control group: periorbital dark circles of one group will be treated with QS laser 3 times at 6-week intervals. Intervention group: periorbital dark circles of the group will be treated with QS laser, fractional CO2 and PRP, 3 times at intervals of 6 weeks.

Main outcome variables

periorbital dark circles; patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N20**

Registration date: **2022-06-24, 1401/04/03**

Registration timing: **prospective**

Last update: **2022-06-24, 1401/04/03**

Update count: **0**

Registration date

2022-06-24, 1401/04/03

Registrant information

Name

Sona Zare

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of simultaneous effect of CO2 laser and QS laser with PRP on periorbital dark circles

Public title

The efficacy of PRP, Erbium laser and QS laser in the treatment of periorbital dark circles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age from 18 to 65 years patient with periorbital dark circles

Exclusion criteria:

Active infection on face Pregnancy Breastfeeding History of cancer structural dark circles or under eye loss of fat

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will be done as single-blind and only the outcome evaluator will be unaware of the treatment method. The patient and the doctor will have enough information about the treatment.

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

Ethics Committee, Technology and Research office, Ghods st., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1372

Health conditions studied

1

Description of health condition studied

periorbital dark circles

ICD-10 code

H02.71

ICD-10 code description

Chloasma of eyelid and periorcular area

Primary outcomes

1

Description

periorbital dark circles

Timepoint

Before, during treatment and 3 months after treatment

Method of measurement

severity of under eye dark halos in comparison to the rest of the face, using Mexameter device.

Secondary outcomes

1

Description

Satisfaction rate

Timepoint

After the last session

Method of measurement

comparing the severity of periorbital dark circles, before and after treatment (score from 0 - 10)

Intervention groups

1

Description

Intervention group: In each session, patients are treated with Q-switched Nd:YAG 1064nm laser, deka fractional CO2 laser and 1 cc injection of PRP, three times with an interval of six weeks.

Category

Treatment - Other

2

Description

Control group: Patients are treated with Q-switched Nd:YAG 1064nm laser three times with an interval of six weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

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

Full name of responsible person

Shiva Alavi

Street address

No 4, Maryam Alley, South Kamraniyeh Street

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

shiva.alavi@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

Central University Organization, sixth floor, Vice
Chancellor for Research and Technology, corner of
Quds Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

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

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

sonazarebio@gmail.com

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

Specialist

Other areas of specialty/work

Dermatology

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

nilforoosh@sina.tums.ac.ir

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

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

sonazarebio@gmail.com

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