

# 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,  
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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**

Specialist

**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**

Sona Zare

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Cellular and Molecular 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