

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

**Comparing the safety and effectiveness of the treatment of dark circles around the eyes by platelet-rich plasma-conditioned medium derived from Wharton jelly mesenchymal stem cells with Q-Switched laser: a randomized clinical trial study.**

### Protocol summary

#### Study aim

Comparing the safety and effectiveness of the treatment of dark circles around the eyes by platelet-rich plasma-conditioned medium derived from Wharton jelly mesenchymal stem cells with Q-Switched laser: a randomized clinical trial study

#### 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 10 patients with periorbital dark circles

#### Settings and conduct

The intervention site is Skin and Stem Cell Research Center of Tehran University of Medical Sciences.

#### 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

Intervention group: patients are treated with Q-switched Nd:YAG 1064nm laser, 0.5 cc conditioned medium injection and 0.5cc PRP injection three times with four weeks interval. Control group: patients are treated with Q-switched Nd:YAG 1064nm laser and 0.5cc PRP injection three times with four weeks interval.

#### Main outcome variables

Periorbital dark circles; patient's satisfaction

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200127046282N40**

Registration date: **2024-06-08, 1403/03/19**

Registration timing: **prospective**

Last update: **2024-06-08, 1403/03/19**

Update count: **0**

#### Registration date

2024-06-08, 1403/03/19

#### 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

2024-06-14, 1403/03/25

#### Expected recruitment end date

2024-09-15, 1403/06/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the safety and effectiveness of the treatment of dark circles around the eyes by platelet-rich plasma-

|                                                                                                                                                                                             |                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| conditioned medium derived from Wharton jelly mesenchymal stem cells with Q-Switched laser: a randomized clinical trial study.                                                              |                                                                                                                                                                                 |
| <b>Public title</b>                                                                                                                                                                         | Tehran                                                                                                                                                                          |
| Comparison of the treatment of dark circles around the eyes by platelet-rich plasma-conditioned medium with Q-Switched laser                                                                | <b>Postal code</b>                                                                                                                                                              |
| <b>Purpose</b>                                                                                                                                                                              | 1417613151                                                                                                                                                                      |
| Treatment                                                                                                                                                                                   | <b>Approval date</b>                                                                                                                                                            |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                         | 2023-11-27, 1402/09/06                                                                                                                                                          |
| <b>Inclusion criteria:</b>                                                                                                                                                                  | <b>Ethics committee reference number</b>                                                                                                                                        |
| Age from 18 to 65 years Patient with periorbital dark circles                                                                                                                               | IR.TUMS.MEDICINE.REC.1402.471                                                                                                                                                   |
| <b>Exclusion criteria:</b>                                                                                                                                                                  |                                                                                                                                                                                 |
| Active infection on face Pregnancy Breastfeeding History of cancer Structural dark circles or under eye loss of fat                                                                         | <b>Health conditions studied</b>                                                                                                                                                |
| <b>Age</b>                                                                                                                                                                                  | <u>1</u>                                                                                                                                                                        |
| From <b>18 years</b> old to <b>65 years</b> old                                                                                                                                             | <b>Description of health condition studied</b>                                                                                                                                  |
| <b>Gender</b>                                                                                                                                                                               | Periorbital dark circles                                                                                                                                                        |
| Both                                                                                                                                                                                        | <b>ICD-10 code</b>                                                                                                                                                              |
| <b>Phase</b>                                                                                                                                                                                | H02.71                                                                                                                                                                          |
| 1-2                                                                                                                                                                                         | <b>ICD-10 code description</b>                                                                                                                                                  |
| <b>Groups that have been masked</b>                                                                                                                                                         | Chloasma of eyelid and periocular area                                                                                                                                          |
| <ul style="list-style-type: none"> <li>Outcome assessor</li> </ul>                                                                                                                          | <b>Primary outcomes</b>                                                                                                                                                         |
| <b>Sample size</b>                                                                                                                                                                          | <u>1</u>                                                                                                                                                                        |
| Target sample size: <b>10</b>                                                                                                                                                               | <b>Description</b>                                                                                                                                                              |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                               | Periorbital dark circles                                                                                                                                                        |
| Not randomized                                                                                                                                                                              | <b>Timepoint</b>                                                                                                                                                                |
| <b>Randomization description</b>                                                                                                                                                            | Before and 3 months after treatment                                                                                                                                             |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                    | <b>Method of measurement</b>                                                                                                                                                    |
| Single blinded                                                                                                                                                                              | severity of under eye dark halos in comparison to the rest of the face, using mexameter device.                                                                                 |
| <b>Blinding description</b>                                                                                                                                                                 |                                                                                                                                                                                 |
| 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. | <b>Secondary outcomes</b>                                                                                                                                                       |
| <b>Placebo</b>                                                                                                                                                                              | <u>1</u>                                                                                                                                                                        |
| Not used                                                                                                                                                                                    | <b>Description</b>                                                                                                                                                              |
| <b>Assignment</b>                                                                                                                                                                           | Satisfaction rate                                                                                                                                                               |
| Parallel                                                                                                                                                                                    | <b>Timepoint</b>                                                                                                                                                                |
| <b>Other design features</b>                                                                                                                                                                | Three months after the last meeting                                                                                                                                             |
|                                                                                                                                                                                             | <b>Method of measurement</b>                                                                                                                                                    |
|                                                                                                                                                                                             | comparing the severity of periorbital dark circles, before and after treatment (score from 0 - 10)                                                                              |
| <b>Secondary Ids</b>                                                                                                                                                                        | <b>Intervention groups</b>                                                                                                                                                      |
| empty                                                                                                                                                                                       | <u>1</u>                                                                                                                                                                        |
| <b>Ethics committees</b>                                                                                                                                                                    | <b>Description</b>                                                                                                                                                              |
| <u>1</u>                                                                                                                                                                                    | Intervention group: patients are treated with Q-switched Nd:YAG 1064nm laser, 0.5 cc conditioned medium injection and 0.5cc PRP injection three times with four weeks interval. |
| <b>Ethics committee</b>                                                                                                                                                                     | <b>Category</b>                                                                                                                                                                 |
| <b>Name of ethics committee</b>                                                                                                                                                             | Treatment - Other                                                                                                                                                               |
| Working Group/Ethics Committee in Research Faculty of Medicine-Tehran University of Medical Sciences                                                                                        | <u>2</u>                                                                                                                                                                        |
| <b>Street address</b>                                                                                                                                                                       | <b>Description</b>                                                                                                                                                              |
| Ethics Committee, Technology and Research office, Ghods st., Keshavarz Blvd.                                                                                                                | Control group: patients are treated with Q-switched Nd:YAG 1064nm laser and 0.5cc PRP injection three times with four weeks interval.                                           |
| <b>City</b>                                                                                                                                                                                 |                                                                                                                                                                                 |
| Tehran                                                                                                                                                                                      |                                                                                                                                                                                 |
| <b>Province</b>                                                                                                                                                                             |                                                                                                                                                                                 |

**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**  
Mohammad Ali Nilforoushzadeh  
**Street address**  
No 4, Maryam Alley, South Kamraniyeh Street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1937957511  
**Phone**  
+98 21 2665 7438  
**Email**  
dr\_nilforoush@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Ali Akbari Sari  
**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  
**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**  
Subspecialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
No 4, Maryam Alley, South Kamraniyeh Street  
**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

**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