

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

**A comparative study of the effectiveness and side effects of using a combination of platelet-rich plasma and adipose-derived stem cells with platelet-rich plasma treatment alone in dark circles around the eyes.**

### Protocol summary

#### Study aim

A comparative study of the effectiveness and side effects of using a combination of platelet-rich plasma and adipose-derived stem cells with platelet-rich plasma treatment alone in dark circles around the eyes.

#### 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 20 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: In each session, patients are treated by injecting half a cc of conditioned medium derived from adipose tissue cells and half a cc of PRP, twice with an interval of four weeks. Control group: In each session, patients are treated by injecting half a cc of normal saline and half a cc of PRP twice with an interval of four weeks.

#### Main outcome variables

Periorbital dark circles; patient's satisfaction

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200127046282N49**

Registration date: **2024-07-10, 1403/04/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-07-10, 1403/04/20**

Update count: **0**

#### Registration date

2024-07-10, 1403/04/20

#### 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

2024-07-10, 1403/04/20

#### Expected recruitment end date

2024-09-20, 1403/06/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparative study of the effectiveness and side effects of using a combination of platelet-rich plasma and adipose-derived stem cells with platelet-rich plasma treatment alone in dark circles around the eyes.

#### Public title

Investigating the combination of platelet-rich plasma and fat-derived stem cells in dark circles around the eyes

### 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: **20**

### 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

Working Group/Ethics Committee in Research Faculty of Medicine-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

2023-11-27, 1402/09/06

## Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.471

## 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 periocular area

## Primary outcomes

### 1

#### Description

Periorbital dark circles

#### Timepoint

Before and 1 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

1 month after the last meeting

#### 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 by injecting half a cc of conditioned medium derived from adipose tissue cells and half a cc of PRP, twice with an interval of four weeks.

#### Category

Treatment - Other

### 2

#### Description

Control group: In each session, patients are treated by injecting half a cc of normal saline and half a cc of PRP twice with an interval of four 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**

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**

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**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

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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

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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