Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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