

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the safety and effectiveness of plasma rich fibrin (PRF) to plasma rich platelet (PRP) in the treatment of periorbital rejuvenation and hyperpigmentation: a randomized double-blind clinical trial study

Protocol summary

Study aim

Evaluation the safety and efficacy of fibrin-rich plasma (PRF) injections in treating aging and dark circles under the eyes compared to platelet-rich plasma (PRP)

Design

This study is a randomized double-blind clinical trial with a control group, conducted on 25 patients, using the simple randomization method.

Settings and conduct

25 patients visiting skin research center will be randomly assigned to two groups. In the first group, they will receive PRP on the left side of the face and RPF on the right side in three sessions, one month apart. The second group will receive RPF on the left side of the face and PRP on the right side in three sessions, one month apart. Finally, the results will be compared between the two groups and between the two sides of the face. It will be conducted in a double-blind manner, where the evaluating physician and the statistical expert will be unaware of the treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 years and above and under 60 years, having darkness and wrinkles in the lower eyelid area, written informed consent for participation in the study exclusion criteria: patients with malignancy, receiving chemotherapy in the past 5 years, patients with sepsis, smoking, pregnancy or breastfeeding, active wound or infection at the treatment site, receiving any medication in the past 3 months for under-eye darkness

Intervention groups

Patients will be randomly assigned to two groups. In the first group (A), patients will receive autologous PRP on the left side of the face and autologous RPF on the right side in three sessions, one month apart. In the second group (B), patients will receive RPF on the left side of the face and PRP on the right side in three sessions, one month apart.

Main outcome variables

Periorbital dark circles; patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N51**

Registration date: **2024-07-20, 1403/04/30**

Registration timing: **registered_while_recruiting**

Last update: **2024-07-20, 1403/04/30**

Update count: **0**

Registration date

2024-07-20, 1403/04/30

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

2024-07-20, 1403/04/30

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the safety and effectiveness of plasma rich fibrin (PRF) to plasma rich platelet (PRP) in the treatment of periorbital rejuvenation and hyperpigmentation: a randomized double-blind clinical trial study

Public title
Comparing the safety and effectiveness of plasma rich fibrin (PRF) to plasma rich platelet (PRP) in the treatment of periorbital rejuvenation and hyperpigmentation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-60
Darkness and wrinkles in the lower eyelid area
Informed consent
Exclusion criteria:
Patients with malignancy
Receiving chemotherapy in the past 5 years
Patients with sepsis
Smoking
Pregnancy or breastfeeding
Active wound or infection at the treatment site
Receiving any topical or systemic medication in the past 3 months for under-eye darkness

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, the method of simple randomization will be used. The randomization sequence will be determined by the researchers before the start of the study, and then sampling will begin. We will have two containers. One container will have 25 numbers from 1 to 25, and the second container will have 25 sealed envelopes indicating which side will receive PRP and which side will receive RPF. The randomization process will proceed as follows: first, a number will be randomly selected from the first container, and then an envelope will be randomly selected from the second container and placed in a designed box. The number drawn from the first container will be paired with the treatment protocol from the envelope drawn from the second container. This process will be repeated for all 25 numbers. Thus, the box will contain 25 numbers, each paired with an envelope containing the treatment. In this method, the type of intervention inside each envelope is unknown, which constitutes randomization concealment. This

means that which side of the face receives which treatment will not be known until the participant arrives and the envelope is opened. The treatments will be labeled as A and B, and only the study designer will know the specifics of treatments A and B

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study will be conducted in a double-blind manner, so that the doctor who scores the results of the study and the patient do not know which treatment group they are placed in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics committee of medical school - Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Keshavarz blvd.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2024-05-01, 1403/02/12

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.047

Health conditions studied

1

Description of health condition studied
Dark circles and wrinkles under the eyes

ICD-10 code
H02.71

ICD-10 code description
Chloasma of eyelid and periorcular area

Primary outcomes

1

Description
Comparing the safety and effectiveness of plasma rich fibrin (PRF) to plasma rich platelet (PRP) in the treatment

of periorbital rejuvenation and hyperpigmentation

Timepoint

In the study investigating the safety and efficacy of injecting fibrin-rich plasma (PRF) in treating aging and dark circles under the eyes compared to platelet-rich plasma (PRP), the time points for measuring dark circles and wrinkles are at 0, 3, 4, and 6 months after the start of the intervention.

Method of measurement

In the study investigating the safety and efficacy of injecting fibrin-rich plasma (PRF) in treating aging and dark circles under the eyes compared to platelet-rich plasma (PRP), the measurement of outcome variables will be done through patient and physician satisfaction questionnaires, as well as through visioface biometric assessments.

Secondary outcomes

1

Description

Satisfaction rate

Timepoint

Three months 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: Patients will receive one cc of PRP and one cc of RPF in the left half of their face in two sessions, one month apart.

Category

Treatment - Other

2

Description

Intervention group: Patients receive one cc of RPF in the left half of the face and one cc of PRP in the right half of the face in two sessions, one month apart.

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

Mohammad Ali Nilforoushzadeh

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