Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 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
Evaluatation 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

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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 periocular 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Central University Organization, sixth floor, Vice Chancellor for Research and Technology, corner of Quds Street, Keshavarz Boulevard

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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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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