Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Efficacy of Platelet-Rich Fibrin (PRF) and Platelet-Rich Plasma (PRP) Injections in the Treatment of Androgenetic Alopecia: A Randomized Clinical Trial

Protocol summary

Study aim
Comparing efficacy of platelet-rich fibrin (PRF) and platelet-rich plasma (PRP) injections for androgenetic alopecia in terms of changes in hair density and thickness, clinical improvement, and adverse events.

Design
A randomized, double-blind, parallel-group clinical trial involving 24 patients with androgenetic alopecia. Participants will be randomly (simple randomization) allocated to two groups of 12 patients receiving PRF or PRP.

Settings and conduct
The study will be conducted at Razi Hospital among patients with androgenetic alopecia. Eligible participants will be randomly allocated to either the PRF or PRP group. Injections will be administered at weeks 0, 4, and 8. Assessments will be performed at baseline, month 3, and month 6 using clinical examination, photography, and trichoscopy. A predefined scalp area with the lowest hair density will be marked for longitudinal assessment. Terminal and vellus hairs will be counted by two dermatologists blinded to treatment allocation, and the mean of their measurements will be recorded.

Participants/Inclusion and exclusion criteria
Patients aged over 18 years with androgenetic alopecia diagnosed by clinical examination and trichoscopy, with active hair loss during the previous 12 months and Hamilton-Norwood grade II–VI or Ludwig grade I–III are eligible; treatment for hair loss during the previous 3 months; previous hair transplantation; systemic disease or scalp disease that may affect hair growth; concomitant treatment for androgenetic alopecia; pregnancy are not eligible.

Intervention groups
PRF group: Intradermal scalp injections of platelet-rich fibrin (PRF) at weeks 0, 4, and 8; PRP group: Intradermal scalp injections of platelet-rich plasma (PRP) at weeks 0, 4, and 8.

Main outcome variables
Change in overall hair density from baseline to the end of the study.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251112067973N4**
Registration date: **2026-09-28, 1405/07/06**
Registration timing: **prospective**

Last update: **2026-09-28, 1405/07/06**
Update count: **0**

Registration date
2026-09-28, 1405/07/06

Registrant information

Name
Yekta Ghane

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5557 5141

Email address
yektaghanemd@gmail.com

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-12-22, 1405/10/01

Expected recruitment end date
2027-06-22, 1406/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Platelet-Rich Fibrin (PRF) and Platelet-Rich Plasma (PRP) Injections in the Treatment of Androgenetic Alopecia: A Randomized Clinical Trial

Public title

Platelet-Rich Fibrin (PRF) and Platelet-Rich Plasma (PRP) Injections in the Treatment of Androgenetic Alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of androgenetic alopecia based on clinical examination and trichoscopy Active hair loss during the preceding 12 months Androgenetic alopecia classified as grade II to VI according to the Hamilton-Norwood scale or grade I to III according to the Ludwig classification Written informed consent

Exclusion criteria:

Any treatment for hair loss during the preceding 3 months History of hair transplantation Systemic or scalp diseases that may affect hair growth Pregnancy Unwilling to participate in the study or continue participation

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

After eligibility has been confirmed according to the predefined inclusion and exclusion criteria, participants will be allocated to the PRF or PRP group using simple randomization. A unique study code will be assigned to each eligible participant, and treatment allocation will be determined according to a pre-generated random sequence. Each participant will have an equal probability of being allocated to either study group. Given the total sample size of 24 participants, 12 participants will be allocated to the PRF group and 12 participants to the PRP group. Group allocation will be performed after confirmation of eligibility and before initiation of the intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

he participants, outcome assessor, and data analyst will be blinded to treatment allocation. Treatment allocation will be performed by an individual independent of outcome assessment and statistical analysis. The outcome assessor will not have access to treatment allocation during clinical assessment and evaluation of the relevant images/outcome measures. The data analyst will analyze the dataset using coded treatment groups without knowledge of the identity or nature of the treatment groups. If required, the allocation codes will be unblinded after completion of outcome assessment and final statistical analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences

Street address

School of Medicine, Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2027-07-25, 1406/05/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1405.230

Health conditions studied

1

Description of health condition studied

Androgenic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Change in overall hair density

Timepoint
before initiation of treatment, and at the third and sixth months after treatment initiation.
Method of measurement
Hair density will be assessed using a trichoscope by counting the number of hairs within a predefined scalp area, with the patient's head maintained in a standardized and fixed position.

Secondary outcomes

1

Description
Change in hair density in the predefined scalp area
Timepoint
before initiation of treatment, and at the third and sixth months after treatment initiation
Method of measurement
Hair density will be assessed using a trichoscope. A predefined circular area with a diameter of 10 millimeters and an area of 100 square millimeters will be evaluated, and the number of hairs within this area will be counted.

2

Description
Change in hair shaft thickness
Timepoint
before initiation of treatment, and at the third and sixth months after treatment initiation
Method of measurement
The mean hair shaft thickness of five hairs within the predefined scalp area will be measured and recorded using trichoscopy in micrometers. Hairs with a thickness greater than 40 micrometers will be classified as terminal hairs, whereas hairs with a thickness less than 40 micrometers will be classified as vellus hairs.

3

Description
Overall Treatment Response Based on Changes in Lesion Density on Clinical Photographs
Timepoint
At baseline before initiation of the intervention and at month 6 after initiation of the intervention.
Method of measurement
Changes in lesion density will be evaluated based on clinical photographs of the participants. Standardized photographs will be obtained in frontal and vertex views with the head maintained in a fixed position. The photographs will be assessed by the participants themselves and by two dermatologists. The degree of change in lesion density will be evaluated using a standardized seven-point grading system: marked decrease in density (−3), moderate decrease in density (−2), mild decrease in density (−1), no change (0), mild increase in density (+1), moderate increase in density (+2), and marked increase in density (+3).

Intervention groups

1

Description
Intervention group: Participants in this group will receive localized scalp injections of platelet-rich plasma (PRP). For PRP preparation, 10–20 mL of venous blood will be collected from each participant into tubes containing sodium citrate (3.2–3.8%) as an anticoagulant. The blood sample will then be centrifuged at 3000 rpm for 12 minutes. Following centrifugation, the platelet-rich plasma fraction will be separated from the other blood components and, if required, activated with 10% calcium chloride prior to injection. The prepared PRP will be administered by localized injection into the predetermined scalp area with the lowest hair density or the margin of the hair-loss area. Injections will be performed at weeks 0, 4, and 8. Participants will be followed throughout the study for treatment response and any potential injection-related adverse events.
Category
Treatment - Other

2

Description
Intervention group: Participants in this group will receive localized scalp treatment with platelet-rich fibrin (PRF). For PRF preparation, 10–20 mL of venous blood will be collected into sterile tubes without the use of any anticoagulant. The blood sample will be immediately centrifuged, within a maximum of 1 minute after collection, at 1500 rpm for 4 minutes. Following centrifugation, three layers will form: a platelet-rich fibrin clot (PRF clot) in the middle, plasma in the upper layer, and red blood cells in the lower layer. After separation, the PRF clot will be used directly or prepared as a membrane when required. The PRF will be administered by localized injection into the predetermined scalp area with the lowest hair density or the margin of the hair-loss area. Treatment will be performed at weeks 0, 4, and 8. Participants will be followed throughout the study for treatment response and any potential injection-related adverse events.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Parisa Sadat Mirsafaei
Street address
Razi Hospital- Vahdate-e-eslami St, Tehran, Iran
City
Tehran
Province

Tehran
Postal code
1199663911
Phone
+98 21 5288 8282
Email
tumspr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
6th Floor, Vice Presidency of Research and Technology Central Administration Building, Tehran University Keshavarz Blvd., at the corner of Qods St. Tehran, Iran
City
Tehran
Province
Tehran
Postal code
141765383761
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
Tehran University of Medical Sciences
Full name of responsible person
Parisa Sadat Mirsafaei
Position
Dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Razi Hospital, Razi Alley, Vahdat-e Eslami St., below Vahdat-e Eslami Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5557 5141
Fax
Email
tumspr@tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Parisa Sadat Mirsafaei
Position
Dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Razi Hospital, Razi Alley, Vahdat-e Eslami St., below Vahdat-e Eslami Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5557 5141
Fax
Email
tumspr@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Parisa Sadat Mirsafaei
Position
Dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Razi Hospital, Razi Alley, Vahdat-e Eslami St., below Vahdat-e Eslami Sq., Tehran, Iran

City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5557 5141
Fax
Email
tumspr@tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
De-identified individual participant data collected during the study, including demographic characteristics, clinical outcome measures, ultrasonographic measurements, treatment allocation, treatment exposure, and safety laboratory data, may be shared upon reasonable request. The shared dataset will not contain directly identifying personal information. Study-related documents, including the study protocol and statistical analysis plan, may also be made available upon reasonable request. Data will not be publicly posted in an identifiable or unrestricted form.
When the data will become available and for how long
Access to de-identified individual participant data and study-related documents will begin 6 months after publication of the primary study results and will remain available for at least 5 years thereafter, subject to ethical and institutional requirements.
To whom data/document is available
Researchers and academic or scientific investigators from universities, research institutions, or other qualified organizations may submit a request for access. Requests from investigators outside academic institutions may also be considered if the proposed use meets the study's ethical and scientific requirements.
Under which criteria data/document could be used
Data may be used for scientifically and ethically appropriate research purposes, including secondary analyses, methodological research, and systematic reviews or meta-analyses. Access will be limited to de-identified data and will not permit attempts to re-identify participants. The proposed use must be consistent with the original informed consent and applicable ethical and institutional requirements. Data may not be used for commercial purposes or redistributed to third parties without prior approval.
From where data/document is obtainable
Requests should be submitted to the principal investigator,
What processes are involved for a request to access data/document
Applicants should submit a written request describing the purpose of the proposed research, the specific data or documents requested, the proposed analyses, and the intended dissemination of the results. Each request will be reviewed by the principal investigator and the research team for scientific merit, ethical compatibility, participant confidentiality, and compliance with institutional requirements. Additional documentation, such as an institutional affiliation or research ethics approval, may be requested when appropriate. Approved data will be provided in a de-identified format after completion of the required review and any applicable data-use agreement. Requests will normally be reviewed within 4 to 8 weeks of receipt of complete documentation.
Comments