

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of platelet-rich plasma alone and in combination with microneedling in the treatment of androgenic alopecia

Protocol summary

Study aim

Determining and comparing the effectiveness of the platelet-rich plasma method alone and in combination with microneedling in the treatment of androgenetic alopecia

Design

Each participant is randomly assigned to one of two groups (A or B) based on their choice from a pool of 60 cards. The population of the present study is the group of men suffering with androgenetic alopecia grades 3, 4 and 5. Demographic information of people referred for the treatment of androgenetic alopecia is recorded. Patients are divided into two groups. A group of these patients are treated with PRP alone. The other group is treated with PRP in combination with microneedling. Beginning and post-treatment photos will be taken after follow-up (1 month) along with dermoscopic evaluation (at two fixed points on the scalp). Dry dermoscopy evaluation will be done using DermLite 4 dermatoscope with 10x magnification in polarized mode. Hair pull test will be done before and 1 month after the follow-up.

Settings and conduct

The analyst does not know which participant belongs to which group, allowing unbiased data analysis. The place of study is Razi Hospital and Imam Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Male patients aged 18 to 60 years old 2- Androgenic alopecia grades 5, 4, and 3 3- Not taking hormonal drugs and supplements Exclusion criteria: 1- Having uncontrolled diabetes 2- Tendency keloid 3- Anticoagulant therapy 4- People who have blood phobia 5- Anemia 6- History of malignancy and immunodeficiency diseases 7- People who have received other treatments such as minoxidil or finasteride 8- People with unreasonable expectations of treatment

Intervention groups

A group of these patients are treated with PRP alone. The

other group is treated with PRP in combination with microneedling.

Main outcome variables

Androgenic alopecia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241001063231N1**

Registration date: **2024-11-19, 1403/08/29**

Registration timing: **registered_while_recruiting**

Last update: **2024-11-19, 1403/08/29**

Update count: **0**

Registration date

2024-11-19, 1403/08/29

Registrant information

Name

Behnaz Rangriz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 6696

Email address

behnazrangriz400@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-15, 1403/08/25

Expected recruitment end date

2025-06-15, 1404/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of platelet-rich plasma alone and in combination with microneedling in the treatment of androgenic alopecia

Public title

Evaluation of platelet-rich plasma alone and in combination with microneedling in the treatment of androgenic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male patients aged 18 to 60 years old Androgenic alopecia grades 5, 4, and 3 Not taking hormonal drugs and supplements

Exclusion criteria:

Having uncontrolled diabetes Tendency keloid Anticoagulant therapy People who have blood phobia Anemia History of malignancy and immunodeficiency diseases People who have received other treatments such as minoxidil or finasteride People with unreasonable expectations of treatment

Age

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

Gender

Male

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization in this study, the participants are divided into blocks, each block contains a number of participants. Participants are randomly assigned to groups (A or B) in each block. Each participant has an equal chance of being assigned to groups A or B. In this study, randomization will be done using SPSS software.

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyst does not know which participant belongs to which group, allowing unbiased data analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Tehran University of Medical Sciences Faculty of Medicine

Street address

Ghods St., Porsina St., Faculty of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1936893813

Approval date

2023-11-29, 1402/09/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.488

Health conditions studied**1****Description of health condition studied**

آلوپسی آندروژنتیک

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes**1****Description**

Hair growth rate

Timepoint

Both groups will receive treatment in three sessions at four-week intervals.

Method of measurement

Beginning and post-treatment photos will be taken after follow-up (1 month) and dermoscopic evaluation (at two fixed points on the scalp). Dry dermoscopy evaluation will be done using DermLite 4 dermatoscope with 10x magnification in polarized mode. A hair pull test will be done before and 1 month after the follow-up.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: A group of these patients will treated with PRP (kits from a fixed company) with a 30-gauge insulin syringe alone.

Category

Treatment - Drugs

2

Description

Intervention group: The other group is treated by applying PRP to the head in combination with microneedling (A6 36-needle device).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Behnaz Rangriz

Street address

Razi Hospital, Vahdat Eslami sq, Vahdat Eslami Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0553

Email

behnazrangriz400@gmail.com

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Behnaz Rangriz

Street address

Imam Khomeini Hospital Complex, end of Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 5563 0553

Email

behnazrangriz400@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Akbari Sari

Street address

Faculty of Medicine, Porsina St., Qods St., Tehran

City

Tehran

Province

Tehran

Postal code

1461884513

Phone

+98 21 8898 9487

Email

tumspr@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

Zahra Saffarian

Position

Assistant Professor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Ghods St., Porsina St., Faculty of Medical Sciences

City

Teharn

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0553

Email

Saffarianz@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Saffarian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Ghods St., Porsina St., Faculty of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0553

Email

Saffarianz@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Saffarian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Ghods St., Porsina St., Faculty of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0553

Email

Saffarianz@yahoo.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

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

Undecided - It is not yet known if there will be 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