

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

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## 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

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## **Person responsible for updating data**

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**Full name of responsible person**

Zahra Saffarian

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Email**

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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**

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