

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jul 2026

### Comparison of the efficacy, side effects, satisfaction and tolerability of platelet-rich plasma injection and microneedling platelet-rich plasma in the treatment of androgenetic alopecia

#### Protocol summary

##### Study aim

Comparison of the efficacy, side effects, satisfaction and tolerability of platelet-rich plasma injection and microneedling platelet-rich plasma in the treatment of androgenetic alopecia

##### Design

This phase 1 study is performed on 20 patients with hair loss. In each session, one group receives PRP as an injection and the other group receives PRP with microneedling. This method will be done once a month for 2 sessions. All patients before the treatment and 2 months after the second visit and photos are taken by digital camera and tricoscan. To determine the extent of improvement and compare the two groups, at the end of the study, photos of patients are examined by two neutral dermatologists. Patients' satisfaction and tolerance are also recorded and the results are compared.

##### Settings and conduct

This project is performed in the skin and stem cell research center of Tehran University of Medical Sciences and without informing the patients from the intervention groups, one group receives PRP by injection and the other group receives PRP with microneedling.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Platelet disorders, thrombocytopenia, patients receiving anticoagulants, patients with malignancy, receiving chemotherapy in the last 5 years, patients with sepsis, smoking, pregnancy, ulcers or active infections at the treatment site, not receiving any topical or systemic drugs in the last 3 months, women with hyperprolactinemia, women with hormonal disorders or polycystic ovaries. Exclusion criteria: Dissatisfaction with continuing treatment for any reason, lack of follow-up, severe allergic reaction to the injection.

##### Intervention groups

In each session, one group receives PRP as an injection

and the other group receives PRP with microneedling.

##### Main outcome variables

The amount of hair loss; side effects; patient's satisfaction; tolerability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200127046282N6**

Registration date: **2022-03-26, 1401/01/06**

Registration timing: **prospective**

Last update: **2022-03-26, 1401/01/06**

Update count: **0**

##### Registration date

2022-03-26, 1401/01/06

##### 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

2022-04-14, 1401/01/25

##### Expected recruitment end date

2022-08-16, 1401/05/25  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Comparison of the efficacy, side effects, satisfaction and tolerability of platelet-rich plasma injection and microneedling platelet-rich plasma in the treatment of androgenetic alopecia  
**Public title**  
Evaluation of the effectiveness of platelet-rich plasma and microneedling platelet-rich plasma on the treatment of hair loss  
**Purpose**  
Treatment  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Platelet disorders, thrombocytopenia, patients receiving anticoagulants, patients with malignancy, receiving chemotherapy in the last 5 years, patients with sepsis, smoking, pregnancy, ulcers or active infections at the treatment site, not receiving any topical or systemic drugs in the last 3 months, women with hyperprolactinemia, women with hormonal disorders or polycystic ovaries  
**Exclusion criteria:**  
Dissatisfaction with continuing treatment for any reason, lack of follow-up, severe allergic reaction to the injection  
**Age**  
From **18 years** old to **50 years** old  
**Gender**  
Both  
**Phase**  
1  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **40**  
**Randomization (investigator's opinion)**  
Not randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Single blinded  
**Blinding description**  
In each session, one group receives PRP as an injection and the other group receives PRP with microneedling.  
**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**  
**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences, Keshavarz blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2021-04-07, 1400/01/18

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.031

## Health conditions studied

### 1

#### Description of health condition studied

Hair loss

#### ICD-10 code

L65.9

#### ICD-10 code description

Nonscarring hair loss, unspecified

## Primary outcomes

### 1

#### Description

The amount of hair loss

#### Timepoint

Before treatment and two month after the last session

#### Method of measurement

Trichoscan

## Secondary outcomes

### 1

#### Description

side effects

#### Timepoint

One week after session

#### Method of measurement

Questionnaire and visit

### 2

#### Description

satisfaction

#### Timepoint

Two months after the last session

**Method of measurement**

Questionnaire and visit

**3****Description**

Tolerability

**Timepoint**

Each session after transplantation

**Method of measurement**

Questionnaire and visit

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

Intervention group: In one group, PRP will be given as an injection in two sessions one month apart.

**Category**

Treatment - Other

**2****Description**

Intervention group: In one group, they will receive PRP with microneedling in two sessions one month apart.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Clinic of Skin and Stem cell Research Center of Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Nilforoushzadeh

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2665 7438

**Email**

Nilforoosh@sina.tums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Skin and Stem Cell Research Center, Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Nilforoushzadeh

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2221 5558

**Email**

Nilforoosh@sina.tums.ac.ir6657438

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Skin and Stem Cell Research Center, 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, 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, Tehran

**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, Tehran  
University of Medical Sciences

**Full name of responsible person**

Masoumeh Roohaninasab

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2665 7438

**Email**

masoomehrohani@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Skin and Stem Cell Research Center, 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, Tehran

**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