

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison of the effectiveness of combined treatment of topical minoxidil and PRP(platelet rich plasma) with topical minoxidil alone in patients with moderate to severe female androgenetic alopecia referred to educational clinics Isfahan University of Medical Sciences

#### Protocol summary

##### Study aim

Investigating the effect of platelet-rich plasma in the treatment of female androgenetic alopecia

##### Design

Clinical trial with control group, with parallel groups, randomized, phase 3 on 60 patients. Block randomization is used for randomization.

##### Settings and conduct

The study is conducted on patients with moderate to severe androgenetic alopecia who refer to the medical centers of Isfahan University of Medical Sciences. After examination, obtaining history and consent, patients who meet the inclusion criteria are randomly divided into two groups. The control group receives 5% topical minoxidil daily, and the intervention group, in addition to the mentioned treatment, is treated with platelet-rich plasma for 3 sessions with one-month intervals. After 6 months from the start of the treatment, the patients are compared and evaluated by means of standard photography and trichogram done at the beginning and end of the treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who are willing to participate in the study. 2. Confirmatory diagnosis of androgenetic alopecia disease by two experts with skin and hair experience. 3. Women aged 18 to 60 years. 4. Moderate to severe hair loss. Criteria for not entering the study: 1. Patients suffering from other types of alopecia (such as alopecia areata, telogen effluvium, anagen effluvium and scarring alopecias). 2. Patients with active psoriasis or active lichen planus due to the positive Köbner phenomenon in these diseases. 3. Any serious systemic disease

##### Intervention groups

The control group receives topical minoxidil, and in the intervention group, in addition to the mentioned case,

they are also treated with platelet-rich plasma.

##### Main outcome variables

Hair thickness, hair density, change of photography score, patient satisfaction

#### General information

##### Reason for update

##### Acronym

(PRP(platelet-rich plasma

##### IRCT registration information

IRCT registration number: **IRCT20221230056991N1**

Registration date: **2023-01-11, 1401/10/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-01-11, 1401/10/21**

Update count: **0**

##### Registration date

2023-01-11, 1401/10/21

##### Registrant information

##### Name

Arezoo Refaghat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 4266 1508

##### Email address

arezoorefaghat@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-26, 1401/10/05

**Expected recruitment end date**

2023-09-22, 1402/06/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of combined treatment of topical minoxidil and PRP(platelet rich plasma) with topical minoxidil alone in patients with moderate to severe female androgenetic alopecia referred to educational clinics Isfahan University of Medical Sciences

**Public title**

Investigating the effect of platelet-rich plasma in androgenetic alopecia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients willing to participate in the study Confirmatory diagnosis of androgenetic alopecia disease by two experts with skin and hair experience Women aged 18 to 60 years Moderate to severe hair loss

**Exclusion criteria:**

Patients suffering from other types of alopecia (such as alopecia areata, telogen effluvium, anagen effluvium and scarring alopecias) Patients with active psoriasis or active lichen planus due to the positive Köbner phenomenon in these diseases Any serious systemic disease

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, the patients will be included in the study by convenience sampling method. Then the patients are randomly divided into 2 main groups. In each group, we use the limited randomization method of the block randomization type, in such a way that the groups consist of 15 blocks of 4, including 2 A and 2 B.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethical Committee of Isfahan University of Medical Sciences

**Street address**

Hazarjarib Street, Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2022-12-25, 1401/10/04

**Ethics committee reference number**

IR.MUI.MED.REC.1401.337

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

Androgenetic alopecia

**ICD-10 code**

L64

**ICD-10 code description**

Androgenic alopecia

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

Increase density and thickness of hair

**Timepoint**

The beginning of the study and 6 months after the start of the study

**Method of measurement**

Trichogram, standard photography

**Secondary outcomes****1****Description**

Patient satisfaction score, doctor satisfaction score

**Timepoint**

The beginning of the study and 6 months after the start of the study

**Method of measurement**

A 10-point questionnaire is assigned for the patient's satisfaction, as well as a 10-point questionnaire that is completed by the doctor based on the comparison of the

standard photography score and the comparison of the trichogram (checking the thickness and density of the hair).

## Intervention groups

### 1

#### Description

Control group: Receive topical minoxidil foam 5% once a day

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Receiving topical minoxidil foam 5% once a day and injecting platelet-rich plasma 3 sessions at one-month intervals

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Al-Zahra Hospital

##### Full name of responsible person

Arezoo refaghat

##### Street address

Sefe Boulevard

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8169663363

##### Phone

+98 31 3620 2020

##### Email

arezoorefaghat@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Vice President of Technology and Research of Isfahan University of Medical Sciences

##### Street address

Hazarjarib St., Isfahan University of Medical Sciences, Building No. 4, Research and Technology Vice-Chancellor of the University

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 5149

##### Email

research@mui.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Arezoo Refaghat

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

Safa Street, Al Zahra Hospital, Skin Clinic

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8168613446

##### Phone

+98 31 3668 8644

##### Email

arezoorefaghat@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Arezoo Refaghat

##### Position

Resident

**Latest degree**

Medical doctor

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Arezoo Refaghat

**Position**

Resident

**Latest degree**

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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**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available