

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of 5% minoxidil and platelet-rich plasma combination with 5% minoxidil solution in androgenetic alopecia.

Protocol summary

Study aim

The aim of this study is to compare the efficacy of combined therapy with minoxidil and platelet-rich plasma (PRP) versus conventional minoxidil monotherapy in patients with androgenetic alopecia referred to Al-Zahra Hospital in Isfahan

Design

This study is a randomized, two-arm, parallel-group, superiority, single-center clinical trial. Eligible patients were randomly allocated into either a combined treatment group (minoxidil + PRP) or a conventional treatment group (minoxidil alone) using a random number table. The sample size was determined based on the study inclusion and exclusion criteria, and outcome assessments were performed uniformly in both groups.

Settings and conduct

The study is conducted at Al-Zahra Hospital in Isfahan, in the dermatology outpatient clinic. Eligible patients are enrolled after obtaining informed consent and are randomly assigned to one of the two treatment groups. All treatment procedures and follow-up assessments are performed under the supervision of a dermatologist.

Participants/Inclusion and exclusion criteria

Patient consent
Diagnosis confirmed by a specialist physician
Age between 18 and 45 years
No pharmacological treatment for alopecia within the past 6 months
No history of cardiovascular disease and no use of antihypertensive medications
No other types of alopecia or any systemic dermatologic disease
No pregnancy, breastfeeding, or menopause in female participants

Intervention groups

The intervention group consists of patients with androgenetic alopecia who receive combined treatment with topical minoxidil and platelet-rich plasma (PRP) injections according to the study protocol

Main outcome variables

hair density, hair thickness, patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251231068515N1**

Registration date: **2026-05-13, 1405/02/23**

Registration timing: **prospective**

Last update: **2026-05-13, 1405/02/23**

Update count: **0**

Registration date

2026-05-13, 1405/02/23

Registrant information

Name

Ali Talaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0042

Email address

alitalaei14@edc.mui.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-06-20, 1405/03/30

Expected recruitment end date

2026-07-21, 1405/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of 5% minoxidil and platelet-rich plasma combination with 5% minoxidil solution in androgenetic alopecia.

Public title

Comparing the effect of 5% minoxidil and platelet-rich plasma combination with 5% minoxidil solution in androgenetic alopecia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient consent
Diagnosis confirmed by a specialist physician
Age between 18 and 45 years
No history of cardiovascular disease and no use of antihypertensive medications
No other types of alopecia or any systemic dermatologic disease
No pregnancy, breastfeeding, or menopause in female participants
No pharmacological treatment for alopecia within the past 6 months

Exclusion criteria:

Development of adverse reactions or hypersensitivity to the treatment
Lack of participant compliance or withdrawal from the study for any reason

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients meeting the inclusion criteria will be randomly allocated into two intervention groups using a random number table before initiation of treatment:
Group 1: Combined therapy with PRP + 5% minoxidil
Group 2: Monotherapy with 5% minoxidil
Participants will remain unaware of their group assignment until the start of the intervention, ensuring initial patient blinding until treatment commencement. Allocation will be performed at a 1:1 ratio without stratification, with each patient having an equal probability of assignment to either group. Note: Given the nature of the intervention (PRP injection), complete patient blinding throughout the study is not feasible. However, outcome assessment (trichoscopy and photography) will be performed by an evaluator blinded to group allocation to minimize bias.

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

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

Street address

hezar jerib Ave

City

isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2025-12-29, 1404/10/08

Ethics committee reference number

IR.MUI.MED.REC.1404.398

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

hair density

Timepoint

before intervention, 6 month after intervention

Method of measurement

trichometer device

2

Description

hair thickness

Timepoint

before intervention, 6 month after intervention

Method of measurement

trichometer device

3

Description

patient satisfaction

Timepoint

6 month after intervention

Method of measurement

Patient satisfaction score with treatment: (based on a 7-point scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: platelet rich plasma, administrated two times with 3 month interval via intradermal scalp injections by a dermatologist under sterile conditions AND topical minoxidil 5%, about 1ml administrated on scalp skin two times per day for 3 months

Category

Treatment - Drugs

2

Description

Control group: topical minoxidil 5%, about 1ml administrated on scalp skin two times per day for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Ali Talaei

Street address

Sofeh Blvd

City

Isfahan

Province

Isfahan

Postal code

7573181746

Phone

+98 903 542 5279

Email

alitalaei14@edc.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Askari

Street address

Hezar jerib Ave

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3668 8138

Email

askari@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

Private

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

Fariba Iraj

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Sofeh Blvd

City

Isfahan

Province

Isfahan

Postal code

7573181746

Phone

+98 31 3822 0000

Email

iraji@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fariba Iraj

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Sofeh Blvd

City

Isfahan

Province

Isfahan

Postal code

7573181746

Phone

+98 31 3822 0000

Email

iraji@med.mui.ac.ir

Dermatology

Street address

Isfahan university of medical science, Hezar Jerib
blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3668 0042

Fax**Email**

alitalaei14@edc.mui.ac.ir

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

Esfahan University of Medical Sciences

Full name of responsible person

Ali Talaei

Position

Student

Latest degree

A Level or less

Other areas of specialty/work**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

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