Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 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 isconducted 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

Isfehan

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

terichometer 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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 Iraji
Position
Professor
Latest degree
Subspecialist
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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
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