

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the effect of platelet-rich plasma injection with 5% minoxidil solution versus 5% minoxidil solution in the treatment of androgenetic hair loss

Protocol summary

Study aim

A comparative study of platelet rich plasma injection with 5% minoxidil solution versus 5% minoxidil solution in the treatment of androgenetic hair loss

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 1 and 2 on 40 patients, with simple randomization method.

Settings and conduct

Basic information including demographic and clinical information is collected through a questionnaire and when the patients visit the skin clinic of Imam Khomeini Hospital in Ahvaz, and the patients are randomly divided into 2 groups of 20 people. The first group is treated with platelet-rich plasma along with 5% minoxidil solution, the second group is treated with 5% minoxidil solution. Patients will receive medicine at 0.1 cc per centimeter for 4 weeks for 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men with hereditary hormonal hair loss, age 18 years or older and less than 50 years, Hamilton score 2 to 5, full patient consent to participate in the project. Exclusion criteria: platelet disorders or thrombocytopenia, patients receiving anticoagulants, and patients with malignancy.

Intervention groups

Patients are randomly divided into 2 groups of 20 people. The first group is treated with platelet-rich plasma along with 5% minoxidil solution, the second group is treated with 5% minoxidil solution.

Main outcome variables

Hair follicle density per unit area, hair follicle thickness, hair follicle cuticle condition, hair follicle length

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110522006543N4**

Registration date: **2023-09-07, 1402/06/16**

Registration timing: **prospective**

Last update: **2023-09-07, 1402/06/16**

Update count: **0**

Registration date

2023-09-07, 1402/06/16

Registrant information

Name

Fateme Tajbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 903 026 8698

Email address

tajbakhsh.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of platelet-rich plasma

injection with 5% minoxidil solution versus 5% minoxidil solution in the treatment of androgenetic hair loss

Public title
Investigating the safety and effectiveness of platelet-rich plasma with 5% minoxidil solution in the treatment of androgenic hair loss.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Men with hereditary hormonal hair loss Age 18 years and above and less than 50 years The rate of hair loss in patients in the form of Hamilton score 2 to 5 in men Complete consent of the patient to participate in the plan
Exclusion criteria:
Having a hematological disorder Iron deficiency anemia Having coagulation disorders Bone marrow aplasia Suffering from sepsis Having cancer

Age
From **18 years** old to **50 years** old

Gender
Male

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients with eligibility criteria will be divided into two groups using a randomized block design. An online website (<https://www.sealedenvelope.com>) is used to generate a random list based on the desired sample size and block size of 4. After creating a list, each patient will be identified with a unique code throughout the study. 20 people are selected for the first intervention group and 20 people for the second intervention group. Then, each number is written on the drug container, which is the same for both groups, and it will be given to the patients by someone other than the interventionist, while the patients are not aware of the contents of the container.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the participant, researcher, doctor, interventionist and evaluator will be unaware of the type of drug until the end of the study. The composition of this medicine is poured into similar containers and they cannot be distinguished from each other in terms of color and smell.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan

City

Ahvaz

Province

Khouzestan

Postal code

6441945781

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1402.069

Health conditions studied

1

Description of health condition studied

Androgenic hair loss

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

Primary outcomes

1

Description

Photography before and after treatment of the hair loss area

Timepoint

Before starting the intervention, each treatment session is monthly for 4 months and also 6 months after the end of the treatment

Method of measurement

Photography with a camera

2

Description

Safety

Timepoint

Before starting the intervention, each treatment session is monthly for 4 months and also 6 months after the end of the treatment

Method of measurement

Doctor's assessment of hair loss, history

3

Description

Efficacy

Timepoint

Before starting the intervention, each treatment session is monthly for 4 months and also 6 months after the end of the treatment

Method of measurement

Doctor's assessment of hair loss, patient's satisfaction, history

Secondary outcomes

1

Description

Side effects

Timepoint

At the beginning of the intervention, monthly for 4 months, once every month, after 6 months

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Injection of platelet-rich plasma with 5% minoxidil solution for 4 weeks, 0.1 cc per centimeter for 3 months.

Category

Treatment - Other

2

Description

Intervention group: 5% minoxidil solution for 3 months by the patient locally

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Imam Khomeini Hospital, Ahvaz

Full name of responsible person

Fateme Tajbakhsh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Fateme Tajbakhsh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable