Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 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

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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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zakerkish-m@ajums.ac.ir
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

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Person responsible for updating data

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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