Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison of the efficacy, safety, tolerability, and satisfaction of PRP injection alone and combination of PRP and SVF injection in the treatment of androgenetic alopecia

Protocol summary

Study aim
Determination of the efficacy, safety, tolerability, and satisfaction of PRP injection alone and combination of PRP and SVF injection in the treatment of androgenetic alopecia

Design
Clinical trial with control group, with parallel groups, single blind, randomized, phase 2-3 on 24 patients. A random number table was used for randomization.

Settings and conduct
24 patients are selected from those referred to Rasoul Hospital dermatology clinic with androgenetic alopecia. With the help of random number table, they are divided into two groups of 12 people.The site of intervention will be the Skin and Stem Cell Research Center.

Participants/Inclusion and exclusion criteria
Inclusion criteria: men and women with androgenetic alopecia; age between 18 to 50 years old; Hamilton score 2 to 5 in men and Ludwig score 1 to 3 in women; patient informed consent. Exclusion criteria: platelet dysfunction; thrombocytopenia; anticoagulant drug use; malignancy; chemotherapy within 5 years; sepsis; smoking; pregnancy; ulcer or infection at the site of treatment; do not receive any topical or systemic medication in the last 3 months; women with hyperprolactinemia; women with hormonal dysfunction or polycystic ovarian disease.

Intervention groups
A group of 12 people receives SVF injection in the first session and another group of 12 people receives PRP injection and microneedling in the first session. The second and third sessions of treatment are equal between both groups and include PRP injection and microneedling in each session. The interval between each treatment session is one month. The total number of therapeutic sessions is three. Patients will be evaluated before the start of treatment and two months after the last treatment session.

Main outcome variables
Alopecia severity; the amount of hair in the telogen phase; hair density; patient satisfaction; physician satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210414050963N1**
Registration date: **2021-07-19, 1400/04/28**
Registration timing: **prospective**

Last update: **2021-07-19, 1400/04/28**
Update count: **0**

Registration date
2021-07-19, 1400/04/28

Registrant information

Name
Seyyedeh Tahereh Rahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6690 9257

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mtaherehrahimi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy, safety, tolerability, and satisfaction of PRP injection alone and combination of PRP and SVF injection in the treatment of androgenetic alopecia

Public title
Comparison of the efficacyof PRP injection alone and combination of PRP and SVF injection in the treatment of androgenetic alopecia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ladies and gentlemen with androgenetic alopecia Age 18 years and above and less than 50 years old Hamilton score 2 to 5 in men Ludwig score 1 to 3 in women Complete patient consent to participate in the project
Exclusion criteria:
Platelet dysfunction Thrombocytopenia Anticoagulant drug use Malignancy Chemotherapy within 5 years Sepsis Smoking Pregnancy Ulcer or infection at the site of treatment Do not receive any topical or systemic medication in the last 3 months Women with hyperprolactinemia Women with hormonal dysfunction or polycystic ovarian disease
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly assigned to one of two study groups using a table of random numbers.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor and data analyst are not aware of the type of intervention performed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2021-04-06, 1400/01/17
Ethics committee reference number
IR.IUMS.FMD.REC.1400.017

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
Alopecia severity
Timepoint
Before start of the trial and two months after the last session
Method of measurement
Rate of change in the clinical severity of alopecia is measured by imaging with visioface. hamilton scale 1 to 6 in men.Ludwig scale 1 to 3 in women

2

Description
The amount of hair in the telogen phase
Timepoint
Before the beginning of the trial and two months after the last session
Method of measurement
The amount of hair in the telogen phase is measured by pull test

3

Description
Hair density
Timepoint
Before the beginning of the trial and two months after the last session
Method of measurement
Hair density is measured by trichoscan

4

Description
Patient satisfaction of treatment
Timepoint
Two months after the last session of treatment
Method of measurement
Patient global assessment score

5

Description
Physician satisfaction of treatment
Timepoint
Two months after the last session of treatment
Method of measurement
Physician global assessment score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: a group of 12 people are treated with SVF injection in the first session. The second and third sessions of treatment include injection and microneedling of platelet-rich plasma in each session. The interval between each treatment session is one month.
Category
Treatment - Drugs

2

Description
Control group: a group of 12 people treated with platelet-rich plasma injection and microneedling in all three treatment sessions. The interval between each treatment session is one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Tahereh Rahimi
Street address
Rasool Akram Hospital, Niayesh street, Shahara
City
Tehran
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1445613131
Phone
+98 21 6690 9257
Email
mtaherehrahimi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Skin and Stem Cell Research Center
Full name of responsible person
Mohammad Ali Nilforoushzadeh
Street address
No 4. Maryam Alley. South Kamranyeh Street, Skin and Stem Cell Research Center
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 2221 2537
Email
Afsaneh.najafi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Skin and Stem Cell Research Center
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
Iran University of Medical Sciences
Full name of responsible person

Seyyedeh Tahereh Rahimi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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Rasool Akram Hospital, Niayesh street, Shahara

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Person responsible for updating data

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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