

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)

Phone

+98 21 6690 9257

Email address

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 efficacy of 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

Province

Tehran

Postal code

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

Street address

Rasool Akram Hospital, Niayesh street, Shahara

City

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+98 21 6690 9257

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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