

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim

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

Design

This phase 1 study is performed on 24 patients with hair loss. In each session, one side is treated with SVF (intervention) injection and the other side is treated with normal saline (control) injection. All patients before the treatment and 2 months after the second visit and photos are taken by digital camera and tricoscan. To determine the extent of improvement and compare the two groups, at the end of the study, photos of patients are examined by two neutral dermatologists. Patients' satisfaction and tolerance are also recorded and the results are compared.

Settings and conduct

This project is performed in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences and without informing the patients, one side receives SVF as an injection and the other group receives normal saline.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women with hereditary hormonal hair loss, age 18 years and older and less than 50 years, Hamilton score 2 to 5 in men and Ludwig score 1 to 3 in women, complete patient consent to participate in the project. Exclusion criteria: platelet disorders, thrombocytopenia, patients receiving anticoagulants, patients with malignancy, receiving chemotherapy in the last 5 years, patients with sepsis, smoking, pregnancy, ulcers or active infections at the treatment site, not receiving any topical medication Or systemic medication in the last 3 months, women with hyperprolactinemia, women with hormonal disorders or polycystic ovaries.

Intervention groups

In each session, one side is treated with SVF (intervention) injection and the other side is treated with normal saline (control) injection.

Main outcome variables

The amount of hair loss; side effects; patient's satisfaction; tolerability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N8**

Registration date: **2022-03-28, 1401/01/08**

Registration timing: **prospective**

Last update: **2022-03-28, 1401/01/08**

Update count: **0**

Registration date

2022-03-28, 1401/01/08

Registrant information

Name

Sona Zare

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-19, 1401/01/30

Expected recruitment end date

2022-08-21, 1401/05/30

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 SVF injection in the treatment of androgenetic alopecia

Public title
Comparison of the efficacy of SVF injection in the treatment of alopecia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 men and women with inherited hormonal hair loss Age 18 years and older and less than 50 years Hamilton scores 2 to 5 in men and Ludwig scores 1 to 3 in women Complete patient consent to participate in the project
Exclusion criteria:
 Platelet disorders Thrombocytopenia Patients receiving anticoagulants Patients with malignancy Receiving chemotherapy during the last 5 years Patients with sepsis Being a smoker Pregnancy Active wound or infection at the treatment site Do not receive any topical or systemic medication in the last 3 months Women with hyperprolactinemia Women with hormonal disorders or polycystic ovaries

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients' heads are randomly divided into two groups. One side is treated with SVF injection and the other side is treated with normal saline injection in 3 sessions 1 month apart.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-09-22, 1400/06/31

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.708

Health conditions studied

1

Description of health condition studied

Hair loss

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

Primary outcomes

1

Description

The amount of hair loss

Timepoint

Before treatment and two month after the last session

Method of measurement

Trichoscan

Secondary outcomes

1

Description

side effects

Timepoint

One week after session

Method of measurement

Questionnaire and visit

2

Description

satisfaction

Timepoint

Two months after the last session

Method of measurement

Questionnaire and visit

3**Description**

Tolerability

Timepoint

Each session after transplantation

Method of measurement

Questionnaire and visit

Intervention groups**1****Description**

Intervention group: One side of the patient's head is treated with SVF injection.

Category

Treatment - Other

2**Description**

Control group: One side of the patient's head is treated with normal saline injection.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

Elham Behrangi

Street address

No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

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1937957511

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Email

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Skin and Stem Cell Research Center, Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

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No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

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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

Skin and Stem Cell Research Center, Tehran 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**

Skin and stem Cell Research Center, Tehran University of Medical Sciences

Full name of responsible person

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Elham Behrangi

Position

Associate professor

Latest degree

Specialist

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Person responsible for updating data

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Name of organization / entity

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Ph.D.

Other areas of specialty/work

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable