

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the efficacy, safety and satisfaction of adipose derived stromal vascular fraction cells injection and 665nm low level diode laser hat in the treatment of androgenetic alopecia

Protocol summary

Study aim

Comparison of the efficacy, safety and satisfaction of adipose derived stromal vascular fraction cells injection and 665nm low level diode laser hat in the treatment of androgenetic

Design

This study is performed in phase 1 and 2 on 30 patients with hair loss. In each session, the first group is treated with SVF injection in three sessions with an interval of one month each. The second group is treated with a laser cap three times a week for 10 minutes each time. The third group is treated with SVF injection in three sessions with an interval of one month each, during which they use a laser helmet three times a week for 10 minutes.

Settings and conduct

This project is performed in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences and patients are divided into three groups: treated with SVF injection, laser cap, SVF injection and laser cap.

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.

Intervention groups

Control group 1: Patients are treated with SVF injections in three sessions, one month apart. Control group 2: Patients are treated with laser caps three times a week for 10 minutes each time. Intervention group: Patients treated with SVF injections are placed in three sessions with an interval of one month each, during which they wear a laser helmet three times a week for 10 minutes.

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: **IRCT20200127046282N16**

Registration date: **2022-05-15, 1401/02/25**

Registration timing: **prospective**

Last update: **2022-05-15, 1401/02/25**

Update count: **0**

Registration date

2022-05-15, 1401/02/25

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

2022-05-31, 1401/03/10

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 and satisfaction of adipose derived stromal vascular fraction cells injection and 665nm low level diode laser hat in the treatment of androgenetic alopecia

Public title

Comparison of the efficacy of Stromal Vascular Fraction injection and ow level laser 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

1-2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Patients are divided into three groups. The first group is treated with SVF injection in three sessions with an interval of one month each. The second group is treated with a laser cap three times a week for 10 minutes each time. The third group is treated with SVF injection in three sessions with an interval of one month each, during which they use a laser helmet three times a week for 10 minutes. The data analyzer was considered blind in this study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics in Biomedical Research of Shahid Beheshti University of medical sciences

Street address

Daneshjoo Blvd, Yaman street

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-04-24, 1401/02/04

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.034

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 one 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

One months after the last session

Method of measurement

Satisfaction Questionnaire and visit

3

Description

Tolerability

Timepoint

Each session after transplantation

Method of measurement

Questionnaire and visit

Intervention groups

1

Description

Control group: Each session, patients are treated with injections of 20 million adipose-derived SVF cells in three sessions, one month apart.

Category

Treatment - Other

2

Description

Control group: Patients are treated with 665 nm laser caps three times a week for 10 minutes each time.

Category

Treatment - Other

3

Description

Intervention group: Patients treated with 20 million injections of adipose-derived SVF cells are placed in three sessions with an interval of one month each, during which they wear a laser helmet three times a week for 10 minutes.

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

Mohammad Ali Nilforoushzadeh

Street address

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

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Phone

+98 21 2665 7438

Email

nilforoosh@sina.tums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sadi Banar

Street address

Laser Application in Medical Sciences Research
Center, Shohadaye-Tajrish Educational Hospital,
Tajrish Sq, Tehran, Iran

City

Tehran

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Tehran

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1989934370

Phone

+98 21 2271 8021

Email

laser.cntr@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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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No 4, Maryam Alley, South Kamraniyeh Street, Tehran

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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

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

Skin and Stem Cell Research Center, Tehran
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Full name of responsible person

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Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

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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