

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Study of safety and effectiveness of mesenchymal stem cells condition medium in the treatment of hair loss (phases I and II)

Protocol summary

Study aim

Study of safety and effectiveness of mesenchymal stem cells condition medium in the treatment of hair loss (phases I and II)

Design

This study is performed as phase 1 and 2 on 45 patients with hair loss. In each session, one side of the patient's head (intervention group) is injected with Wharton jelly mesenchymal stem cells conditioned medium, and the other side of the head (control group) with physiological serum is injected. This method will be performed once a month for 3 months. All patients are photographed before the treatment and in each session by digital camera and tricoscan. To determine the extent of recovery and compare the two sides of the head, at the end of the study, photos of patients are examined by two neutral dermatologists. Patient satisfaction is 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 patient of the intervention groups, one side of the head is used for Wharton jelly mesenchymal stem cells conditioned medium and the other side is used for blinding physiological serum in areas of hair loss.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-60, patients with hair loss, Patients who do not want to take or are allergic to minoxidil. Exclusion criteria: Individuals who have used any product or medication during the previous 6 months that may affect hair growth, Pregnancy and breastfeeding History of cancer, People with Mental Disorders, Active infection of the scalp.

Intervention groups

Intervention group: One side of the head mesenchymal stem cells conditioned medium is injected. control group: The other side of the head is injected physiological serum as a control group.

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N13**

Registration date: **2022-05-01, 1401/02/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-01, 1401/02/11**

Update count: **0**

Registration date

2022-05-01, 1401/02/11

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

2022-04-14, 1401/01/25

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
Study of safety and effectiveness of mesenchymal stem cells conditioned medium in the treatment of hair loss (phases I and II)

Public title
Evaluation of the safety and effectiveness of mesenchymal stem cells conditioned medium in the treatment of hair loss

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who do not want to take minoxidil. Patients who are allergic to minoxidil.
Exclusion criteria:
The patient has used an effective drug in hair loss during the last 6 months.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
At each session on one side of the head, mesenchymal stem cells conditioned medium and on the other side of the head, saline solution is injected. Participants and data analysts will not know about the intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz blvd

City

Tehran

Province

Tehran

Postal code

1937957511

Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.999

Health conditions studied

1

Description of health condition studied

Hair loss

ICD-10 code

L65.9

ICD-10 code description

Nonscarring hair loss, unspecified

Primary outcomes

1

Description

The amount of hair loss

Timepoint

Before starting treatment, end of the first, second, third month and one month after the end of the treatment period (end of the fourth month)

Method of measurement

Trichoscan

Secondary outcomes

1

Description

side effects

Timepoint

Before starting treatment, end of the first, second, third month and one month after the end of the treatment period (end of the fourth month)

Method of measurement

Questionnaire and visit

2

Description

effectiveness

Timepoint

Before starting treatment, end of the first, second, third month and one month after the end of the treatment period (end of the fourth month)

Method of measurement

Questionnaire and visit

Intervention groups

1

Description

Control group: One side of the physiological serum is injected. This will be done once a month for 3 months.

Category

Treatment - Other

2

Description

Intervention group: Wharton jelly mesenchymal stem cells conditioned medium is injected on the side of the head. This will be done once a month for 3 months.

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

Dr_nilforoush@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

Central University Organization, sixth floor, Vice
Chancellor for Research and Technology, corner of
Quds Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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 of 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

sonazarebio@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

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

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

A Level or less

Other areas of specialty/work

Dermatology

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

Dr_nilforoush@yahoo.com

Street address

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

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

sonazarebio@gmail.com

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

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

Skin and Stem cell Research Center of 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