

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation the efficacy of mesenchymal stem cells condition medium on hair transplantation outcome

Protocol summary

Study aim

Evaluation the efficacy of mesenchymal stem cells condition medium on hair transplantation outcome

Design

This study is performed as phase 1 and 2 on 30 hair transplant patients. Two weeks after transplantation, conditioned medium is injected and sprayed 5 times subcutaneously at the operation site 5 times in the intervention group and in the control group. 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 Jordan Clinic and two weeks after transplantation, in the intervention group, conditioned medium is injected 5 times two weeks apart and in the control group, PRP is injected subcutaneously at the operation site.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for hair transplantation, no internal diseases other than hypothyroidism, no use of drugs that cause hair loss such as chemotherapy, psychotropic drugs, anticoagulants, cardiovascular, retinoids, antimicrobials, lack of androgenic hormones Psychiatry such as obsessive-compulsive disorder and trichotillomania, absence of active infection in the transplant area, age between 18-50 years. Exclusion criteria: unwillingness to continue co-operation, pregnancy, lactation, exposure to acute and severe stress during the study, xylocaine allergy

Intervention groups

Two weeks after transplantation, conditioned medium is injected and sprayed 5 times subcutaneously at the operation site 5 times in the intervention group and in the control group.

Main outcome variables

The result of hair transplantation; side effects; Patient satisfaction; Wound healing rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N18**

Registration date: **2022-06-05, 1401/03/15**

Registration timing: **prospective**

Last update: **2022-06-05, 1401/03/15**

Update count: **0**

Registration date

2022-06-05, 1401/03/15

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

2022-06-20, 1401/03/30

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the efficacy of mesenchymal stem cells condition medium on hair transplantation outcome

Public title
Evaluation the efficacy of stem cells condition medium on hair transplantation outcome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Candidate hair transplant patients Absence of internal diseases except hypothyroidism Do not take drugs that cause hair loss such as chemotherapy, psychotropic drugs, anticoagulants, cardiovascular, retinoids, antimicrobials, androgen hormones Absence of psychiatric diseases such as obsessive-compulsive disorder and trichotillomania Absence of active infection in the transplanted area Age between 18-50 years
Exclusion criteria:
 Reluctance to continue cooperation Pregnancy Breastfeeding Exposure to acute and severe stress during the study Allergy to xylocaine

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

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients participating in this study and analyzing the data are unaware of the study groups. Therefore, the study will be double-blind.

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

Keshavarz blvd, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1937957511

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1373

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

Hair recovery rate

Timepoint

Before treatment and six months 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

Intervention groups

1

Description

Intervention group: Two weeks after the hair transplant, 3 cc stem cells condition medium is injected

subcutaneously five times every two weeks at the transplant site and sprayed a little.

Category

Treatment - Other

2

Description

Control group: Two weeks after the hair transplant, 3 cc platelet rich plasma is injected subcutaneously five times every two weeks at the transplant site and sprayed a little.

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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Postal code

1937957511

Phone

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Email

Dr_nilforoush@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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 of 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

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

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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

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Researcher

Latest degree

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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