

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of safety and efficacy of Wharton's jelly mesenchymal stem cells conditioned medium and Platelet-Rich Plasma (WJMSCs CM-PRP) and liposomal Wharton's jelly mesenchymal stem cells conditioned medium-Platelet-Rich Plasma (Liposomal WJMSCs CM-PRP) in androgenetic alopecia

Protocol summary

Study aim

Comparison of safety and efficacy of Wharton's Jelly mesenchymal stem cells conditioned medium and Platelet-Rich Plasma (WJMSCs CM-PRP) and liposomal Wharton's Jelly mesenchymal stem cells conditioned medium-Platelet-Rich Plasma (Liposomal WJMSCs CM-PRP) in androgenetic alopecia

Design

Patients are randomly divided into two groups. The first group receives CM-PRP injection and the second group receives topical liposomal CM-PRP. Injections will be given in three sessions with an interval of one month and topical use will be every day for up to three months. The amount of clinical improvement is determined by 2 blind doctors by comparing the photos of the patients before and after the treatment. Before starting the treatment, at the end of the first, second, third month and one month after the end of the treatment period (the end of the fourth month), a biometric examination will be done and the findings from VISIOFACE and TES-TB) will be recorded for each patient.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Inclusion criteria: AGA type 2-4, no use of topical or oral medication for the treatment of alopecia during the last six months Exclusion criteria: Age under 18 years, pregnancy, breastfeeding, history of malignant diseases, use of any local or systemic treatment during the research.

Intervention groups

Intervention group: patients will use liposomal conditioned medium-platelet rich plasma daily for three

months. Control group: patients will receive conditioned medium-platelet rich plasma product three times with an interval of one month as an injection.

Main outcome variables

Hair density

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N24**

Registration date: **2023-02-18, 1401/11/29**

Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**

Update count: **0**

Registration date

2023-02-18, 1401/11/29

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

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of safety and efficacy of Wharton's jelly mesenchymal stem cells conditioned medium and Platelet-Rich Plasma (WJMSCs CM-PRP) and liposomal Wharton's jelly mesenchymal stem cells conditioned medium-Platelet-Rich Plasma (Liposomal WJMSCs CM-PRP) in androgenetic alopecia

Public title

Comparison of the safety and efficacy of the combination of Wharton's jelly mesenchymal stem cells conditioned medium and platelet-rich plasma and liposomal of Wharton's jelly mesenchymal stem cells conditioned medium and platelet-rich plasma in the treatment of androgenetic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Not using topical or oral medication for the treatment of alopecia during the last six months AGA type 2-4

Exclusion criteria:

Age under 18 years pregnancy breastfeeding History of malignant diseases Taking any topical or systemic treatment during the study

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

- Care provider

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Balanced Randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

Two dermatologists who are responsible for comparing the photos of patients before and after treatment.

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 Boulevard,

City

Tehran

Province

Tehran

Postal code

1937957511

Approval date

2022-10-03, 1401/07/11

Ethics committee reference number

1401.531.IR.TUMS.REC.MEDICINE.REC

Health conditions studied**1****Description of health condition studied**

Androgenetic alopecia

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

Primary outcomes**1****Description**

Hair density

Timepoint

Before starting the treatment, the 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

Biometric examination will be done and the findings from VISIOFACE and TES-TB (hair loss type with X1 lens, hair density and scalp condition with X60Triple lens, hair diameter and PORE condition with KPL X150 lens and hair shaft surface condition with X700 lens) It will be recorded for each patient

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

Intervention group: patients will use liposomal conditioned medium-platelet rich plasma daily for three months.

Category

Treatment - Other

2

Description

Control group: patients will receive conditioned medium-platelet-rich plasma product three times with an interval of one month as an injection.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

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

Full name of responsible person

Mohammad Ali Neel Farushzadeh

Street address

No. 4, Maryam Alley, South Kamraniye St., Tehran

City

TEHRAN

Province

Tehran

Postal code

1937957511

Phone

+98 21 2668 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 Fatuhi

Street address

floor 6th vice president of research and technology,
corner of Qods St., Central University Organization,
Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 8163 3698

Email

ir.ac.tums@vcr

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

Tehran University of Medical Sciences

Full name of responsible person

Sona Zare

Position

Research fellow

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

Street address

No. 4, Maryam Alley, South Kamraniye St.

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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Nilforoushzadeh
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
No. 4, Maryam Alley, South Kamraniye St.
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2665 7438
Email
Dr_nilforoush@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person

Sona Zare
Position
Research fellow
Latest degree
Ph.D.
Other areas of specialty/work
Cellular and Molecular Biology
Street address
No. 4, Maryam Alley, South Kamraniye St.
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

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