Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 under18 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