Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Investigating the Safety and Efficacy of Umbilical Cord Blood Serum Derived Extracellular Vesicles versus Autologus Platelet Rich Plasma and Minoxidil for Treatment of Androgenic Alopecia

Protocol summary

Study aim

Investigating the level of safety and effectiveness of extracellular vesicles derived from umbilical cord blood serum in comparison with the platelet-rich autologous plasma group and the minoxidil group in the treatment of androgenic hair loss.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 1 and 2 on 30 patients, randomization: simple randomization method

Settings and conduct

Basic information, including demographic and clinical information, is collected through a questionnaire and when the patients visit the SSRC of Tehran University of Medical Sciences, and the patients are randomly divided into 3 groups of 10 people. The first group was treated with umbilical cord blood serum, the second group was treated with autologous PRP and the third group was treated with minoxidil topically, in groups 1 and 2 patients for 4 sessions with 1 month intervals. They are treated by injections. Patients will be examined with the following methods in each treatment session and 3 and 6 months after the completion of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women and men with hereditary hormonal hair loss, age 18 years or 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 or thrombocytopenia, patients receiving anticoagulants, patients with malignancy.

Intervention groups

Patients are randomly divided into 3 groups of 10 people. The first group was treated with extra vesicles derived from umbilical cord blood serum, the second group was treated with autologous PRP, and the third group was treated with topical minoxidil.

Main outcome variables

Hair follicle density per surface unit, hair follicle thickness, hair follicle cuticle condition, hair follicle length

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221130056672N1**
Registration date: **2023-06-21, 1402/03/31**
Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**
Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

EHSAN Taghiabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-23, 1402/10/02

Expected recruitment end date

2024-01-22, 1402/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Safety and Efficacy of Umbilical Cord Blood Serum Derived Extracellular Vesicles versus Autologus Platelet Rich Plasma and Minoxidil for Treatment of Androgenic Alopecia

Public title

Safety and Efficacy of Umbilical Cord Blood Serum Derived Extracellular Vesicles versus for Treatment of Androgenic Alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women and men with hereditary hormonal hair loss Age 18 years and above and less than 50 years The rate of hair loss in patients is Hamilton score 2 to 5 in men and Ludwig score 1 to 3 in women. Complete consent of the patient to participate in the study

Exclusion criteria:

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization. There is no stratified randomization. Randomization tool: using simple randomization method, patients who refer to Dr. Nilfroosh Zadeh's skin clinic are divided into 3 groups. In this way, out of the 30 sealed envelopes, one envelope is randomly selected for each patient. Inside each envelope is the letter A, B or C. Group A patients will be treated with extra vesicles, group B will be treated with PRP, and group C patients will be treated with minoxidil.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participant, the researcher, the relevant doctor and nurse, and the evaluating doctor will be unaware of the type of treatment until the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Deputy Research and Technology Office, 6th Floor, Central Organization of Tehran University of Medical Sciences, Qods St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1416613675

Approval date

2023-06-19, 1402/03/29

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1402.018

Health conditions studied

1

Description of health condition studied

Androgenic Alopecia

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

Primary outcomes

1

Description

The number of hair follicles using the Trichoscan device, the thickness of the hair follicle using the Trichoscan device

Timepoint

Before the start of the intervention, each treatment session is monthly for 4 months and also 6 months after the end of the treatment.

Method of measurement

Findings from VISIOFACE and TES-TB (low hair 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

Secondary outcomes

1

Description
Safety and Efficacy
Timepoint
At the beginning of the intervention, monthly for 4 months, every one month, after 6 months.
Method of measurement
Patient's history, examination, hair diameter, number of hair per surface unit, patient's satisfaction level.

Intervention groups

1

Description
The first group was treated with extra vesicles derived from umbilical cord blood serum with a selected concentration, the second group was treated with autologous PRP by injection, and the third group was treated with minoxidil topically.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Skin and Stem Cell Research Center, Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Nilforoushzadeh
Street address
No 4 Maryam Dead End South Kamraniyeh, Andarzgo Blvd, Tehran Province, Tehran.
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https://skinstemcell.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Nilforoushzadeh
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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
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
Ehsan Taghiabadi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after de-identifying individuals.

When the data will become available and for how long
Six months after the publication and printing of the article

To whom data/document is available
Academic researchers and experts

Under which criteria data/document could be used
In order to analyze data related to study outcomes

From where data/document is obtainable
etaghiabadi@sina.tums.ac.ir

What processes are involved for a request to access data/document
It can be submitted after review by the Research Council of the Skin and Stem Cell Research Center of Tehran University of Medical Sciences, which usually takes 2 to 3 months.

Comments