Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

15- Investigating the safety and effectiveness of the injection of conditioned medium derived from keratinocyte and fibroblast cells forascin compared to platelet rich plasma in the treatment of androgenic alopecia: a blinded randomized controlled interventional study

Protocol summary

Study aim
Investigating the safety and effectiveness of the injection of conditioned medium derived from keratinocyte and fibroblast cells forascin compared to platelet rich plasma in the treatment of androgenic alopecia: a blinded randomized controlled interventional study

Design
A clinical trial with a control group, with a parallel group, double-blind, Randomized, phase 3 on 24 patients. To randomize from the table Random numbers were used.

Settings and conduct
This study is conducted in Rasul Akram hospital center in Tehran. The doctor who scores the results of the study and the statistician do not know which treatment group the patient is in. 1. Determining the severity of alopecia based on Ludwig criteria in female pattern or Hamilton criteria in male pattern 2. Imaging: every appointment, patients are photographed with the Vizioface device and trichoscopy of the hair loss areas. 3.Patient global assessment score: which is completed by the patient based on the level of satisfaction with the treatment with the same scale above

Participants/Inclusion and exclusion criteria
Entry criteria: 1- men and women with hereditary hormonal hair loss, 2-over 18 years old and less than 50 years, 3- Hamilton score 2 to 5 in men and Ludwig score 1 to 3 in women, 4- full patient consent to participate in the project. Exclusion criteria : 1- platelet disorders or thrombocytopenia 2- patients receiving anticoagulants, 3- patients with malignancy 4-receiving chemotherapy in the last 5 years 5- women with hormonal disorders or polycystic ovaries.

Intervention groups
Treatments will be A and B. Group A will be treated with conditioned medium and the second group will be treated with PRP

Main outcome variables
Hair count and hair thickness. Standard photographic score by the doctor It is reported. Patient satisfaction score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221026056309N1**
Registration date: **2022-11-08, 1401/08/17**
Registration timing: **prospective**

Last update: **2022-11-08, 1401/08/17**
Update count: **0**

Registration date
2022-11-08, 1401/08/17

Registrant information

Name
Nastaran Kabiri Samani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 86701

Email address
nastarankabiri61@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-21, 1401/08/30

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

15- Investigating the safety and effectiveness of the injection of conditioned medium derived from keratinocyte and fibroblast cells forascin compared to platelet rich plasma in the treatment of androgenic alopecia: a blinded randomized controlled interventional study

Public title

Investigating the effect of conditioning medium in the treatment of alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women with hereditary hormonal hair loss Hamilton score 2-5 in men and Ludwig score 1-3 in women Complete consent of the patient to participate in the plan

Exclusion criteria:

Platelet disorders or thrombocytopenia Patients receiving anticoagulants Receiving any topical or systemic medication in the last 3 months for hair loss

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

We will have 2 containers. In one of the containers, there will be 24 numbers from 1 to 24, and in vase number 2, there will be 24 sealed envelopes, in which the desired type of treatment is inserted. The process of randomization will be that first we will choose a number randomly from the first container and we will choose an envelope randomly from the second container and put them in a designed box. The number removed from container #1 will take the treatment that was removed from container #2. We will do this for all 24 numbers. That is, we will have 24 numbers in the desired box, and in front of each number there will be an envelope with treatment inside. In this method, the type of intervention that exists inside each envelope is unclear, which is the randomization concealment method. In fact, the treatment assigned to the numbers is not known until the person comes and the envelope is opened for him, and secondly, the names of the treatments will not be clear inside the envelopes, and the names of the treatments will be A and B, and only the study designer He will know about the type of treatment A and B

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study will be conducted in a double-blind manner, so that the doctor who scores the results of the study and the statistician do not know which treatment group the patient is placed in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Medicine of University of Iran

Street address

Tehran Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-05-22, 1401/03/01

Ethics committee reference number

IR.IUMS.FMD.REC.1401.096

Health conditions studied

1

Description of health condition studied

Androgenic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Number of hairs

Timepoint

At the beginning of the study and 3 and 6 months after

the end of the study

Method of measurement

by the hair analyzer

2

Description

Hair thickness

Timepoint

At the beginning of the study and 3 and 6 months after the end of the study

Method of measurement

by the hair analyzer

3

Description

Patient satisfaction score of treatment

Timepoint

At the beginning of the study and 3 and 6 months after the end of the study

Method of measurement

Using a standard scoring scale

4

Description

The doctor's score is based on changing the standard photos

Timepoint

3 and 6 months after completion of treatment

Method of measurement

Using a standard scoring scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group is treated with conditioned medium for 4 sessions with 1 month intervals. 4 ml of concentrated culture medium is used for each injection. Injection is done intradermally in areas with hair loss at half to one centimeter intervals using a 27-gauge insulin syringe. conditioned medium is derived from keratinocyte and fibroblast forascin cells.

Category

Treatment - Drugs

2

Description

Control group: The control group is treated with PRP for 4 sessions with 1 month intervals. 4 ml is used for each injection. Injection is done intradermally in areas with hair loss at half to one centimeter intervals using a 27-gauge insulin syringe.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Elham Behrangi

Street address

Tehran Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

elham.behrangi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Matolian

Street address

Tehran Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

research-m@iums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Stem Cell Research Center

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
Iran University of Medical Sciences

Full name of responsible person
Elham Behrangi

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
Tehran Hemat Highway next to Milad Tower

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 86701

Email
elham.behrangi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Elham Behrangi

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
Tehran Hemat Highway next to Milad Tower

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 86701

Email
elham.behrangi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Nastaran Kabiri Samani

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
ran Hemat Highway next to Milad Tower

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 86701

Email
Nastarankabiri61@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
Not applicable