

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Clinical trial of safety and effectiveness of subcutaneous injection of placenta Growth factors in the treatment of androgenetic alopecia

Protocol summary

Study aim

Investigating the safety and effectiveness of human placenta growth factors' injection in the treatment of androgenic alopecia compared to the placebo group

Design

A phase 1-2 double blinded, randomized, controlled clinical trial with 30 patients. Randomization is in simple form.

Settings and conduct

In this study, 30 patients referred to Razi Hospital in Tehran who meet the inclusion criteria and do not meet the exclusion criteria are evaluated. After obtaining informed consent from the patient, the questionnaire will be completed by the physician. Before starting the treatment and during the follow-up sessions, the number of hairs in the same area is counted using trichoscopy. Patients are treated with drugs or placebo in two groups. The physician, the patient and the evaluator will not know the type of intervention. In total, patients will be treated for 5 sessions. Injections are done every 2 weeks and the patient will return for follow-up at 0, 2, 4, 6, 8, 12 and 24 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Androgenic alopecia, male aged 18 to 50 years, Norwood Hamilton grading 2 to 5. Exclusion criteria: Patients with two or more hair loss diagnoses, hair loss treatment during the last 3 months, patients undergoing radiotherapy and chemotherapy, immunosuppressive drugs or corticosteroids during 4 weeks before treatment

Intervention groups

Intervention group: Subcutaneous injection of a solution containing growth factors obtained from the human placenta. Placental growth factors of 1.5 mg/ml, 3 ml per session, and 5 times at an interval of 2 weeks are injected into the patients. The placental growth factors is obtained by chemically and mechanically digestion in a clean room. Control group: subcutaneous injection of normal saline, 5 times with two-week intervals

Main outcome variables

Primary outcome: side effects Secondary outcome: hair density

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051545N4**

Registration date: **2022-12-05, 1401/09/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-05, 1401/09/14**

Update count: **0**

Registration date

2022-12-05, 1401/09/14

Registrant information

Name

Amir Bajouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2221 2537

Email address

bajouri.md@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of safety and effectiveness of subcutaneous injection of placenta Growth factors in the treatment of androgenetic alopecia

Public title
Placenta growth factors in the treatment of androgenetic alopecia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with androgenetic alopecia Age 18 to 50 years
 Male Norwood-Hamilton grade II to V
Exclusion criteria:
 Patients with two or more diagnoses of hair loss
 Treatment of hair loss in the last 3 months
 Patients undergoing radiotherapy and chemotherapy
 Immunosuppressive drugs or corticosteroids during the previous 4 weeks
 Uncontrolled chronic diseases
 Malignancy
 Coagulopathy or the use of anticoagulants
 History of autoimmune diseases
 HBV, HCV and HIV infections

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

Gender
Male

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
The randomization method is simple. For 30 patients, 30 interventions including 15 drugs and 15 placebos are considered and a code is defined for each intervention. Then for each patient based on the table of random numbers, a code that may be drug or placebo is selected. The drug or placebo is sent to the physician in a disguised form and the physician performs the injection based on the assigned code.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients, researchers, physician, nurse and outcome evaluator are blinded until the end of the study. For this purpose, a code is assigned to the drug or placebo, and based on the table of random numbers, a code is selected and the drug or placebo is sent to the physician in a covered form with a code. The physician administers the injection to the patient. The patient's

medical record is defined as a code, and the patient and the evaluator will not know the type of medicine.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Medical School, Tehran
University of Medical Sciences

Street address

1st floor, Faculty of Medicine, Building No. 1, Poursina St., Qods St, Elkhebal St.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-10-30, 1401/08/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.572

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

Side effects

Timepoint

Injection day, and 2 weeks, 1, 2, 4 and 6 months after first injection

Method of measurement

History and clinical examination based on Common Terminology Criteria for Adverse Events criteria

Secondary outcomes

1

Description

Frontal and vertex hair density

Timepoint

1, 2, 4, and 6 months after the first injection

Method of measurement

Digital videotrichoscopy

Intervention groups

1

Description

Intervention group: Subcutaneous injection of the solution containing growth factors obtained from the human placenta is performed in 15 patients with androgenic alopecia. Placental growth factors at the rate of 1.5 mg per ml, 3 ml per session, and 5 times at an interval of 2 weeks are injected into the patients. The placental growth factors are obtained by mechanically and chemically digestion in clean room of ViraCellule company, and the necessary quality control tests are performed on the mother and the final sample. Treatment follow-ups are done in the first and second weeks and in the second, fourth, and sixth months after the injection.

Category

Treatment - Drugs

2

Description

Control group: Physiological serum is injected in the amount of 3 ml per session and 5 times with an interval of 2 weeks in 15 patients with hair loss. Follow-up is done in the first and second week and in the second, fourth and sixth months after the injection.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi skin hospital

Full name of responsible person

Maryam Nasimi

Street address

Razi Dead End, Vahdat Islami Square, Vahdat Islami St.

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Province

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1199663911

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nsm.maryam@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

6th floor, Central Organization of the University, corner of Quds St., Keshavarz Blvd.

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Email

vcr@tums.ac.ir

Web page address

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

Amir Bajouri

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Medical Biotechnology

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Person responsible for scientific inquiries

Contact

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Position
Associate professor
Latest degree
Specialist
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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

Information on the main outcome

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Scientific research

From where data/document is obtainable

Amir Bajouri bajouri.md@gmail.com

What processes are involved for a request to access data/document

The request is sent through the official email of the university, mentioning the recipient's information and the purpose of the request, and after checking the correctness of the information sent, the files are provided to the requester.

Comments