Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Clinical trial of safety and effectiveness of subcutaneous injection of placenta extract in the treatment of androgenetic hair loss

Protocol summary

Study aim

Investigating the safety and effectiveness of human placenta extract injection in the treatment of androgenic hair loss compared to the placebo group

Design

A phase 1-2 double blinded, randomized, controlled clinical trial with 30 patients.

Settings and conduct

In this study, 30 patients referred to Razi Hospital 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 treatment area is counted using trichoscopy. The patient is evaluated during each visit. In total, patients will receive 5 sessions of treatment. Injections are done every 2 weeks and the patients will be followed-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, uncontrolled chronic diseases, malignancy, coagulopathy or anticoagulants, autoimmune diseases, HIV، HCV, or HBV

Intervention groups

Intervention group: Subcutaneous injection of a solution containing growth factors and essential amino acids obtained from the human placenta. Placental extract of 1.5 mg/ml, a total volume of 3 ml per session, and 5 times at an interval of 2 weeks are injected into the patients. The placental extract is obtained mechanically 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: **IRCT20210612051545N5**
Registration date: **2022-12-30, 1401/10/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-30, 1401/10/09**
Update count: **0**

Registration date

2022-12-30, 1401/10/09

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

2022-11-22, 1401/09/01

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 extract in the treatment of androgenetic hair loss

Public title
Placenta extract in the treatment of androgenetic hair loss

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 samples will be randomized according to block randomization design with block size of 4 using Random Allocation Software. In this regard, using the software, the allocation sequence is generated based on the selected block type. Blocking and allocation sequence will be done for concealment by a person which is not involved in the research. The allocation ratio of the samples will be 1:1 and will be placed in two groups receiving drug and placebo. Then based on the obtained blocks and sequence of allocation, drug or placebo will be given to the patients by the sealed enveloped method.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients, researcher, physician, nurse and the evaluator are blinded until the end of the study. For this purpose, a code is assigned to the drug or placebo and it is sent to the physician in a covered form with a code. The physician performs the injection for the patient based on the table of random numbers. 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
2022-10-01, 1401/07/09

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.488

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
zero 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 including fibroblast growth factors, insulin growth factors, and essential amino acids obtained from the human placenta is performed in 15 patients with androgenic alopecia. Placental extract at the rate of 1.5 mg per ml and a total volume of 3 ml per session and 5 times at an interval of 2 weeks is injected into the patients. The placental extract is obtained mechanically in clean room of ViraCellule company, and the necessary quality control tests are performed on the mother and the final sample. Treatment follow-up is 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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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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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 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