

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

clinical study of a personalized therapy based on mesenchymal stem cell extract in hair regeneration in patients with alopecia.

Protocol summary

Study aim

Evaluation of the effectiveness of personalized therapy based on mesenchymal stem cell extract in patients with alopecia.

Design

it's a randomized double blind three-arm parallel study. 60 patients are enrolled in this study. participants are randomly assigned to one of the three groups through block randomization method using randomized numbers.

Settings and conduct

The topical solution will be prepared based on Extract of MSCs (3% stem cell extract in DS water) or placebo (DS water+ Glycerin) for daily uses.(2ml/day) The duration of treatment is 16 weeks. variables will be measured day 1, week 8th, week 16th. patients who receive the non-personalized MSCs Extract, Patients who receive placebo and The physician who is responsible for the evaluation of intervention are blinded.

Participants/Inclusion and exclusion criteria

The patients who aged 18-59 years old with Previous diagnosis of Androgenic alopecia are included in this study. Medications or supplements intake that can affect hair growth. (including finasteride, or any other hormonal products),History of any surgical procedure on the scalp for the treatment of hair loss, History of hyperthyroidism or hypothyroidism, Current pregnancy or breastfeeding, History of allergic reactions to topical medications are defined as exclusion criteria.

Intervention groups

the study is a three-arm trial. Patients who receive personalized MSCs Extract, Patients who receive the non-personalized MSCs Extract and Patients who receive placebo.

Main outcome variables

hair follicle densimeter variables will be measured using hair scanner

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221105056398N1**

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

Registration timing: **prospective**

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

Update count: **0**

Registration date

2022-12-05, 1401/09/14

Registrant information

Name

fatemeh soleymani

Name of organization / entity

Faculty of Medical Sciences, Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-10, 1401/10/20

Expected recruitment end date

2023-06-10, 1402/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

clinical study of a personalized therapy based on mesenchymal stem cell extract in hair regeneration in patients with alopecia.

Public title

personalized therapy based on mesenchymal stem cell extract in alopecia.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Previous diagnosis of Androgenic alopecia. those who aged 18-59 years old.

Exclusion criteria:

Medications or supplements intake that can affect hair growth. (including finasteride, or any other hormonal products) History of any surgical procedure on the scalp for the treatment of hair loss History of hyperthyroidism or hypothyroidism Current pregnancy or breastfeeding History of allergic reactions to topical medications

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization method using randomized numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Using a placebo for the control group. individuals in both placebo and non-personalized stem cell extract groups are blinded and go through the same process and receive a product with the same design, packaging and appearance. The physician who is responsible for the evaluation of intervention is blinded. the personalized study arm is not capable of blinding due to the need to perform a scalp biopsy for this group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research ethic committees Tarbiat Modares university

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Jalal AleAhmad , Nasr

City

Tehran

Province

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Postal code

1411713116

Approval date

2022-10-29, 1401/08/07

Ethics committee reference number

IR.MODARES.REC.1401.156

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 hair in bald area

Timepoint

day 1, week 8th and week 16th;

Method of measurement

Phototrichogram (hair scanner)

2**Description**

Hair diameter and Hair thickness

Timepoint

day 1, week 8th and week 16th;

Method of measurement

Phototrichogram (hair scanner)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients who receive personalized MSCs extract

Category

N/A

2

Description

Intervention group: patients who receive the non-personalized MSCs extract

Category

N/A

3

Description

Control group: patients who receive placebo

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tasvire Javani Clinic For Skin & Hair Transplantation

Full name of responsible person

Mohsen Pirouz Hashemi

Street address

Tasvirejavani Clinic for Skin and Hair Transplantation,
Unit: 16 Number: 128 Tarabandeh alley, South Gandhi
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Email

mphhtc@gmail.com

Web page address

<https://tasvirejavani.com/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pars igene Ltd. Co.

Full name of responsible person

Mehrdad Noruzinia

Street address

unit6, No.132 , Vozara st , Tehran , Iran

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Parsigene@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pars igene Ltd. Co.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Medical Sciences, Tarbiat Modares
University

Full name of responsible person

Fatemeh Soleymani

Position

Research assistant

Latest degree

Master

Other areas of specialty/work

Medical Genetics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

results of the main outcomes after de-identification of participants

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

academic researcher

Under which criteria data/document could be used

The request must be approved by Parsigene Company.

From where data/document is obtainable

contact via email: parsigene@gmail.com

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

Applicants will submit a personal resume and purpose of access to Parsigene Co. email address. the request will be reviewed within 3 weeks.

Comments