Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
+98 21 8866 2821
Email address
f.solimani@modares.ac.ir

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
Street address
Jalal AleAhmad , Nasr
City
Tehran
Province
Tehran
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 Gandi Street. Vanak Square,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
04 48 680 0912
Phone
+98 21 8865 3104
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
City
Tehran
Province
Tehran
Postal code
1516748617
Phone
+98 21 8866 2821
Fax
+98 21 8867 1507
Email
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
Street address
Unit 6, No.132 , Vozara st
City
Tehran
Province
Tehran
Postal code
1516748617
Phone
+98 21 8866 2821
Fax
+98 21 8867 1507
Email
f.solimani@modares.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Medical Sciences, Tarbiat Modares University
Full name of responsible person
Mehrdad noruzinia
Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Genetics

Street address

Unit6, No.132, Vozara st

City

تهران

Province

Tehran

Postal code

1516748617

Phone

+98 21 8670 5503

Email

mehrdad.noruzinia@gmail.com

Person responsible for updating data

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

Street address

Unit6, No.132, Vozara st, Tehran, Iran

City

تهران

Province

Tehran

Postal code

1516748617

Phone

+98 21 8866 2821

Email

roshsoleymani@gmail.com

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