

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Safety and efficacy assessment of PLURYAL® Hair Density intradermal gel, for treatment of male and female pattern androgenic alopecia

Protocol summary

Study aim

Safety and effectiveness assessment of intradermal Pluryal gel containing polynucleotide in the treatment of androgenic hair loss with male and female pattern

Design

The study is a phase 2 before-after clinical trial. The sample size is 20. The study was not randomized.

Settings and conduct

The study will be conducted in center for research and training in skin diseases and leprosy. Participants will be treated in 10 Injection sessions with Pluryal gel. Assessment will be performed first injection session (visit 0), week 6 and week 24 including improvement assessment using Hair lost Changes, based on Global photographic review.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female aged 18-50 years, general health, male with hair loss status II, III, IV Based on Norwood Scale, Female with mild to moderate hair loss pattern, based on Ludwig scale (I and II), voluntary participation and signing written informed consent
Exclusion criteria: Chronic active scalp disease other than hair loss, using any prescribed drug or OTC for hair loss within the past 3 months, documented sensitivity to formulation components, any severe weight loss or strict diet therapy during the study

Intervention groups

10 injection sessions in superficial dermis of the scalp using PLURYAL® Hair Density formulation, product of MD skin solution laboratories, Luxemburg Each prefilled syringe contains 2 ml of isotonic gel consisting of 15mg polynucleotides, water for injectable preparations 1st month: 4 injections with one-week intervals (4 injections) - Months 2, 3, and 4: one injection every 2 weeks (6 injections)

Main outcome variables

Hair lost Changes, based on Global photographic review

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N15**

Registration date: **2022-04-27, 1401/02/07**

Registration timing: **prospective**

Last update: **2022-04-27, 1401/02/07**

Update count: **0**

Registration date

2022-04-27, 1401/02/07

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8190

Email address

firozali@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy assessment of PLURYAL® Hair Density intradermal gel, for treatment of male and female pattern androgenic alopecia

Public title

Safety and effectiveness assessment of Pluryal gel in the treatment of androgenic hair loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female aged 18-50 years General health Male with mild-moderate androgenic alopecia (II-IV Norwood Hamilton Scale) Female with mild-moderate androgenic alopecia (I-II Ludwig Scale) Voluntary participation and signing written informed consent

Exclusion criteria:

Chronic active scalp disease other than hair loss Using any prescribed drug or OTC for hair loss within the past 3 months Documented sensitivity to formulation components Any severe weight loss or strict diet therapy during the study

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-04-18, 1401/01/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.039

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

Hair lost Changes, based on Global photographic review

Timepoint

First injection session (visit 0), week 6 and week 24

Method of measurement

One independent dermatologist will perform clinical assessments by scoring every photograph according to the Global photographic review scale .

Secondary outcomes

1

Description

Hair count changes

Timepoint

First injection session (visit 0), week 6 and week 24

Method of measurement

Trichoscopy By Fotofinder

Intervention groups

1

Description

Intervention group: 10 injection sessions in superficial dermis of the scalp using 2 ml PLURYAL® Hair Density formulation, product of MD skin solution laboratories, Luxemburg Each prefilled syringe contains 2 ml of isotonic gel consisting of 15mg polynucleotides, water for injectable preparations 1st month: 4 injections with one-week intervals (4 injections)- Months 2, 3, and 4: one injection every 2 weeks (6 injections)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for research and training in skin diseases and leprosy

Full name of responsible person

Aniseh Samadi

Street address

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabesh Gostar Mehyad

Full name of responsible person

Mohammadmahdi Khashe chi

Street address

Unit. 4, No. 7, Kordbacheh Alley, Khorramshahr St., Sohrevardi St.

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Postal code

1553635715

Phone

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Email

tgm@tabeshgostar.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabesh Gostar Mehyad

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**

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Manager of Clinical Laboratory

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Proffesor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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firozali@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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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

Not applicable

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