Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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, LuxemburgEach prefilled syringe contains 2 ml of isotonic gel consisting of 15mg polynucleotides, water for injectable preparations1st 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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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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1553635715

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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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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
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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