Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Sep 2026

Clinical investigation of the safety and effectiveness of Excilia Hair strengthening and ani hair loss Lotion in improving male pattern androgenic hair loss

Protocol summary

Study aim

Clinical investigation of the safety and effectiveness of Excilia Hair strengthening and ani hair loss Lotion in improving male pattern androgenic hair loss

Design

Single group, phase 2, before -after clinical study. sample size is 25. The study is not randomized.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 25 healthy volunteers will be selected and enrolled in the study after signing consent form. Volunteers are taught to use Topically use of Excilia Hair strengthening and anti-hair loss lotion for 24 weeks. Before intervention, 8,16,24 and 32 weeks after the start of use changing in hair lost will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male aged 18-55 years General health Hair Loss Status II, III, IV Based on Norwood 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 Oral or topical treatment of minoxidil within 6 months before entering the study.

Intervention groups

Topically use of Excilia Hair strengthening and anti-hair loss lotion; Includes: Minoxidil oxathiazolidine carboxylate 5%, glycolic acid (AHA), caffeine, etc. for 24 weeks.

Main outcome variables

Count changes in terminal hair

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N6**
Registration date: **2023-02-12, 1401/11/23**
Registration timing: **prospective**

Last update: **2023-02-12, 1401/11/23**
Update count: **0**

Registration date

2023-02-12, 1401/11/23

Registrant information

Name

Taraneh Yazdanparast

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

drtaraneh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical investigation of the safety and effectiveness of Excilia Hair strengthening and ani hair loss Lotion in improving male pattern androgenic hair loss

Public title
Clinical investigation of the safety and effectiveness of Excilia Hair strengthening and ani hair loss Lotion in improving hair loss

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male aged 18-55 years General health Hair Loss Status II, III, IV Based on Norwood 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 Oral or topical treatment of minoxidil within 6 months before entering the study.

Age
From **18 years** old to **55 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **25**

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 The Institute of Pharmaceutical Sciences of Tehran University of Medical Science

Street address
Unit 1-219, 2nd floor,The Institute of Pharmaceutical Sciences, Faculty of Pharmacy,16 Azar Avenue

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2023-01-30, 1401/11/10

Ethics committee reference number
IR.TUMS.TIPS.REC.1401.105

Health conditions studied

1

Description of health condition studied
Hair loss

ICD-10 code
L65.9

ICD-10 code description
Nonscarring hair loss, unspecified

Primary outcomes

1

Description
Count changes in terminal hair

Timepoint
Before intervention, 8,16,24 and 32 weeks after the start of use

Method of measurement
Trichoscopy By Fotofinder device

Secondary outcomes

1

Description
Hair count changes

Timepoint
Before intervention, 8, 16 and 32 weeks after the start of use

Method of measurement
Trichoscopy By Fotofinder device

2

Description
Hair lost Changes, based on Global photographic review

Timepoint
Before intervention, 8, 16 and 32 weeks after the start of use

Method of measurement
One independent dermatologist will perform clinical assessments in a blinded fashion by scoring every photograph according to the "Global photographic review" scale.

Intervention groups

1

Description
Intervention group: Topically use of Excilia Hair strengthening and anti-hair loss lotion; Includes: Minoxidil oxathiazolidine carboxylate 5%, glycolic acid (AHA), caffeine, etc. for 24 weeks.
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.
City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 0658
Email
dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zist orchid pharmed Company
Full name of responsible person
Araz Sabzevari
Street address
No 42, Atar street, Boostan alley, Kavoosieh Ave
City
Tehran
Province
Tehran
Postal code
1994766411
Phone
+98 21 4347 3000
Email
ask@orchidpharmed.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zist orchid pharmed Company
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
Taraneh Yazdanparast
Position
Research Physician
Latest degree
Ph.D.
Other areas of specialty/work
Dermatology
Street address
No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue
City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 2220
Email
drtaraneh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Alireza Firooz
Position
Professor of dermatology
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue
City
Tehran
Province
Tehran
Postal code
1416613675
Phone

+98 21 8897 7921

Email

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

Master

Other areas of specialty/work

Dermatology

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 0658

Email

ahmadi.maryam648@gmail.com

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

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