

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Safety and efficacy of topical finasteride nanoemulgel 0.25% in the treatment of mild to moderate androgenetic alopecia on male and female pattern

Protocol summary

Study aim

Safety and efficacy of topical finasteride nanoemulgel 0.25% in the treatment of mild to moderate androgenetic alopecia on male and female pattern

Design

Single group, phase 2, before -after clinical study. sample size is 40. 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, 40 healthy volunteers will be selected and enrolled in the study after signing consent form. Volunteers are taught to use topical finasteride nanoemulgel 0.25% once in a day for 24 weeks. Before intervention, 2, 4 and 6 months after the start of treatment changing in hair lost will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female aged 20-50 years, Hair Loss Status II, III, IV Based on Norwood Scale for men, Hair Loss Status I,II Based on Ludwick Scale for women, General health, Voluntary participation and signing written informed consent Exclusion criteria: Chronic active scalp disease other than hair loss, Using any prescribed drug or over-the-counter(OTC) for hair loss within the past 3 months, Women with abnormal hormonal tests, Women with Polycystic ovary(PCO), pregnancy or lactating women

Intervention groups

Treatment with topical finasteride nanoemulgel 0.25% in scalp area, once in a day for 24 weeks. This emulgel is prepared by high-speed homogenization method with nanoemulsion containing finasteride, which is prepared by materials such as lecithin, vitamin E, chloroform solvent, gelling, cholesterol, PEG 600 and distilled water.

Main outcome variables

Hair count changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190210042676N22**

Registration date: **2022-05-13, 1401/02/23**

Registration timing: **prospective**

Last update: **2022-05-13, 1401/02/23**

Update count: **0**

Registration date

2022-05-13, 1401/02/23

Registrant information

Name

Aniseh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

a_samadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of topical finasteride nanoemulgel 0.25% in the treatment of mild to moderate androgenetic alopecia on male and female pattern

Public title

Safety and efficacy of topical finasteride nanoemulgel 0.25% in the treatment of mild to moderate androgenetic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female aged 20-50 years Hair Loss Status II, III, IV Based on Norwood Scale for men Hair Loss Status I,II Based on Ludwig Scale for women General health Voluntary participation and signing written informed consent

Exclusion criteria:

Chronic active scalp disease other than hair loss Using any prescribed drug or over-the-counter(OTC) for hair loss within the past 3 months Women with abnormal hormonal tests Women with Polycystic ovary(PCO) pregnancy or lactating women

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 in research of medical school- Tehran University of Medical Sciences

Street address

Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-09-15, 1400/06/24

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.664

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

Hair count changes

Timepoint

Before intervention, 2, 4 and 6 months after the start of treatment

Method of measurement

Trichoscopy by Fotofinder

Secondary outcomes

1

Description

Changes in the ratio of anagen to telogen hair

Timepoint

Before intervention, 2, 4 and 6 months after the start of treatment

Method of measurement

Trichoscopy by Fotofinder

Intervention groups

1

Description

Intervention group: Treatment with topical finasteride nanoemulgel 0.25% in scalp area, once in a day for 24 weeks. This emulgel is prepared by high-speed homogenization method with nanoemulsion containing finasteride, which is prepared by materials such as lecithin, vitamin E, chloroform solvent, gelling, cholesterol, PEG 600 and distilled water.

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) Street, Taleqani Avenue

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1416613675

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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbar Fotouhi

Street address

Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical

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afotouhi@tums.ac.ir

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Manger of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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

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aniseh_samadi@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

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

Master

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