Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of efficacy and safety of nanostructured lipid carriers loaded with Dutasteride and pumpkin seed oil and oily solution containing Dutasteride and pumpkin seed oil for androgenic hair loss pattern

Protocol summary

Study aim
Examining efficacy and safety of lipid nanostructures loaded with dutasteride and pumpkin seed oil on volunteers with androgenic alopecia

Design
Two arm parallel group, not randomized, not blinded, trial with phase 2-3 on 24 healthy valunteers

Settings and conduct
Applied Pharmaceutical Research Center of Tabriz Medical Sciences. 24 healthy male volunteers, aged 20 to 70, who have mild to moderate androgenic alopecia. The front of the volunteer's head is divided into two parts, in one area of oil formulation and in one area of nano formulation, it is used once every three days for 6 months. Volunteers will be selected from among friends, acquaintances and relatives

Participants/Inclusion and exclusion criteria
Inclusion criteria: male volunteers diagnosed with mild to moderate androgenic alopecia. Be between 20-70 years old. People who agreed to the informed consent form. Exclusion criteria: receiving any prescription of finasteride and its anti-androgen properties 8 weeks before starting Dutasteride, history of malignancy other than non-melanotic cancers, any diagnosis of global hair thinning or any other scalp or hair disease, history of infertility and varicocele, simultaneous use of Over-the-counter corticosteroids, anabolic steroids, or "hair restorers." Light or laser treatment of the scalp in the last 3 months, previous correction of hair loss surgery, scars, sensitivity and local infections in the scalp

Intervention groups
Volunteers use topical oily and nano formulations for 6 months; At the beginning, in the third month and in the sixth month, they fill out a questionnaire, an imaging of the head area is done, and they are examined by a doctor

Main outcome variables
New hair growth; Area hair density; Hair thickness; Hair growth rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130313012810N52**
Registration date: **2025-02-15, 1403/11/27**
Registration timing: **prospective**

Last update: **2025-02-15, 1403/11/27**
Update count: **0**

Registration date
2025-02-15, 1403/11/27

Registrant information

Name
Hamed Hamishehkar

Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-21, 1404/02/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of nanostructured lipid carriers loaded with Dutasteride and pumpkin seed oil and oily solution containing Dutasteride and pumpkin seed oil for androgenic hair loss pattern

Public title

Dutasteride and Pumkin seed oil loaded nanostructured lipid carrier(NLC) in angrogenic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male volunteers diagnosed with mild to moderate androgenic alopecia Be between 20-70 years old People who agreed to the informed consent form

Exclusion criteria:

Receiving any prescription of finasteride and its anti-androgen effect 8 weeks before starting dutasteride History of malignancy other than non-melanotic cancers Any diagnosis of global hair thinning or any other scalp or hair disease History of infertility and varicocele Concomitant use of corticosteroids, anabolic steroids, or over-the-counter "hair restorers." Light or laser treatment of the scalp in the last 3 months Previous correction of hair loss surgery Scars, sensitivity and local infections in the scalp

Age

From **20 years** old to **70 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Faculty of Pharmacy - Tabriz University of Medical Sciences

Street address

Attar Nishaburi St, Golgasht St.

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Postal code

5166414766

Approval date

2024-10-27, 1403/08/06

Ethics committee reference number

IR.TBZMED.PHARMACY.REC.1403.052

Health conditions studied

1

Description of health condition studied

Androgenic Alopecia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hair growth and hair density of area

Timepoint

Measurement of hair growth at the beginning, 3 and 6 months after the start of the study

Method of measurement

Questionnaire, Head imaging and Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group will take nanostructured lipid carriers containing dutasteride and pumpkin seed oil on the forehead every three days for six months.

Category

Treatment - Drugs

2

Description

Control group: The second group will use an oily solution containing dutasteride and pumpkin seed oil on the forehead every three days for six months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Applie Research Center of Pharmaceutical Sciences
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available