Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical evaluation of the safety and effectiveness Oral capsules (containing minoxidil, finasteride and biotin) in the prevention and treatment of androgenic hair loss

Protocol summary

Study aim
Clinical evaluation of the safety and effectiveness Oral capsules (containing minoxidil, finasteride and biotin) in the prevention and treatment of androgenic hair loss

Design
Single group, phase 2, before -after clinical study. sample size is 20. 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, 20 healthy volunteers will be selected and enrolled in the study after signing consent form. Volunteers are taught to use Oral capsules (containing minoxidil, finasteride and biotin) once a day for 16 weeks. Before intervention and at the end of 8 and 16 weeks later changing in hair lost will be measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male aged 18-50 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

Intervention groups
Intervention group: Daily use of oral anti-hair loos capsules containing 5 mg of biotin, 1 mg of finasteride, 1 mg of minoxidil as active ingredients more over lactose monohydrate as oxypian, for 16 weeks

Main outcome variables
Hair lost Changes, based on Global photographic review

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190210042676N18**
Registration date: **2022-02-08, 1400/11/19**
Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**
Update count: **0**

Registration date
2022-02-08, 1400/11/19

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
2022-02-19, 1400/11/30

Expected recruitment end date
2022-09-21, 1401/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical evaluation of the safety and effectiveness Oral capsules (containing minoxidil, finasteride and biotin) in

the prevention and treatment of androgenic hair loss

Public title
Clinical evaluation of the safety and effectiveness Oral capsules in the prevention and treatment of hair loss
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male aged 18-50 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
Age
From **18 years** old to **50 years** old
Gender
Male

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
Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761

Approval date
2022-01-15, 1400/10/25
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1214

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 lost Changes, based on Global photographic review
Timepoint
Before intervention, 8 and 16 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 .

Secondary outcomes

1

Description
Hair count changes
Timepoint
Before intervention, 8 and 16 weeks after the start of use
Method of measurement
Trichoscopy By Fotofinder

Intervention groups

1

Description
Intervention group: Intervention group: Daily use of oral anti-hair loos capsules containing 5 mg of biotin, 1 mg of finasteride, 1 mg of minoxidil as active ingredients more over lactose monohydrate as oxypian, for 16 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
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No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Knowledge-based company of Janus
Full name of responsible person
Saman Ahmad Nasrollahi
Street address
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Phone
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Email
headoffice@januspharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Knowledge-based company of Janus
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 updating data

Contact
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Tehran University of Medical Sciences
Full name of responsible person
Maryam Ahmadi
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Research Expert
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Master
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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