

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Clinical investigation of the safety and effectiveness of Topaz hair strengthening solution in preventing and improving male pattern androgenic hair loss

Protocol summary

Study aim

Clinical investigation of the safety and effectiveness of Topaz hair strengthening solution in preventing and improving male pattern 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 Topically use of topaz hair strengthening solution twice in a day for 12 weeks. Before intervention and at the end of 6 and 12 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: Topically use of topaz hair strengthening solution; Includes: octapeptide 2, caffeine, B vitamins, amino acids, zinc and herbal extracts (Ginseng, Arctium, etc.) twice in a day for 12 weeks.

Main outcome variables

Hair lost Changes, based on Global photographic review

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N5**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **prospective**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

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

2022-12-22, 1401/10/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical investigation of the safety and effectiveness of Topaz hair strengthening solution in preventing and

improving male pattern androgenic hair loss

Public title

Clinical investigation of Topaz hair strengthening solution in preventing and improving 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 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

2022-11-16, 1401/08/25

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.079

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, 6 and 12 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, 6 and 12 weeks after the start of use

Method of measurement

Trichoscopy By Fotofinder device

Intervention groups

1

Description

Intervention group: Topically use of topaz hair strengthening solution; Includes: octapeptide 2, caffeine, B vitamins, amino acids, zinc and herbal extracts (Ginseng, Arctium, etc.) twice in a day for 12 weeks.

Category

Treatment - Other

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
Qeshm Rojin Company
Full name of responsible person
Fuad Parsa
Street address
No. 1, Aseman Alley, West Rose St., Ferdows Blvd.,
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fuad@parsa.im
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qeshm Rojin 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
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Person responsible for scientific inquiries

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Professor of 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
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Position
Research Expert
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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

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