Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the Effectiveness of Nanostructured Lipid Carriers Containing Lavender Essential Oil Compared to 2% Minoxidil for Androgenic Hair loss; Clinical Trial

Protocol summary

Study aim

Evaluating the Effectiveness of Lipid Nanostructures Containing Lavender Essential Oil Compared to 2% Minoxidil in Androgenic Hair loss

Design

Controlled Clinical trial, with Parallel group, Unblinded and Non-Randomized, Phase 2 and 3 on 20 Patients

Settings and conduct

Male individuals who refer to Sina Hospital in Tabriz with Symptoms of Frontal-temporal Hair loss will be Included in the Study if they agree and meet the Eligibility Criteria (Inclusion Criteria). Volunteers will be Instructed on the Correct Use (The Study is not Blinded). In a Symmetrical manner, Minoxidil 2% will be Used on One side of the Head and a Formulation of Lipid Nanostructures containing Lavender Essential oil on the other side. Necessary Photographs will be taken before the Start, 12 Weeks after the Start, and After the End of the Intervention, and then the Images will be Analyzed by a Physician.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male Subjects with progressive Hair loss in the Fronto-temporal Region. Exclusion criteria: Any Manifestation of Skin Disease in the Study area, Allergy to Pharmaceutical Products or Components of the Study Product, History of Skin Cancer, Acute or Chronic Disease that could interfere with the Study, use of Topical or Systemic Medications or Cosmetic Products that could interfere with the Study.

Intervention groups

Intervention group: Lavender Essential oil contains Compounds that Increase Hair growth and Hair Density. The Duration of the Intervention is 24 weeks, in which on One Side, the Formulation of Lipid Nanostructures of Lavender Essential oil is used one Night a week in an Amount of 1 cc in an Area of 1 cm in Diameter that has been previously Determined. Control group: Minoxidil 2% will be Used once a Day in an Amount of 1 cc in an Area of 1 cm in Diameter.

Main outcome variables

Percentage Change in Hair Density per unit of selected Area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241015063373N1**
Registration date: **2025-01-08, 1403/10/19**
Registration timing: **retrospective**

Last update: **2025-01-08, 1403/10/19**
Update count: **0**

Registration date

2025-01-08, 1403/10/19

Registrant information

Name

Mahsa Farshidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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farshidimahsa8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-31, 1403/08/10

Expected recruitment end date

2024-11-07, 1403/08/17

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the Effectiveness of Nanostructured Lipid Carriers Containing Lavender Essential Oil Compared to 2% Minoxidil for Androgenic Hair loss; Clinical Trial

Public title
Effect of Lavender Essential Oil Formulation on Hair loss
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male Sex Progressive Symptoms of Hair loss in the Frontotemporal Area
Exclusion criteria:
Any Manifestation of Skin Disease in the Study Area Allergy or Hypersensitivity Reaction to Medicinal Products or Components of the Study Product History of Skin Cancer Acute or Chronic Disease that could Interfere with the Study Use of Topical or Systemic Medications or Cosmetic Products that could Interfere with the Study
Age
From **25 years** old to **65 years** old
Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
Lipid Nanostructures Containing Lavender Essential Oil are applied to One Side of the Scalp and 2% Minoxidil is applied to the Opposite Side of the Scalp.
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
Medical Sciences Research Committee of Tabriz, Attar neyshabouri Ave., Golgasht Blvd.
City
Tabriz
Province
East Azarbaijan
Postal code
5165687386
Approval date
2024-09-29, 1403/07/08
Ethics committee reference number
IR.TBZMED.PHARMACY.REC.1403.039

Health conditions studied

1

Description of health condition studied
Androgenic Alopecia
ICD-10 code
L64
ICD-10 code description
Androgenic alopecia

Primary outcomes

1

Description
Percentage Change in Hair Density per unit of Specified Scalp Area
Timepoint
Before the Start of the Intervention, 12 Weeks after the Start of the Intervention, immediately after the End of the Intervention (24 weeks)
Method of measurement
Dermatoscope Device, Yinama Model, Made in China

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the Intervention Group, Lipid Nanostructure Formulation Containing Lavender Essential Oil will be used. In order to prepare Lipid Nanostructures, a High-speed Homogenization Method is used using a Homogenizer. The Formulation of Lipid Nanostructures Containing Lavender Essential Oil is made in the Laboratory of the Tabriz Faculty of Pharmacy. To prepare this Formulation, 400 mg of

Lavender Essential oil as a Liquid Phase, 600 mg of Precirol as a Solid Phase, and 250 mg of Ploxamer as a Surfactant are used. (The Steps of Producing Lipid Nanostructures are briefly written.) Lavender essential Oil contains Compounds that cause the Expression of Factors that Increase Hair Growth and Hair Density. The Intervention Period is 24 weeks, in which 2% Minoxidil Manufactured by Pak Darou Company is used on One Side and a Formulation of Lipid Nanostructures Containing Lavender Essential Oil is used on the Other side at Two Symmetrical Points on the Head. The Desired Formulation will be applied One Night a week in an Amount of 1 cc in a Pre-determined Area of 1 cm in Diameter. The necessary Photographs will be taken by Dermatoscope at times Zero, 12 weeks and 24 weeks after the Start, and the Images will be analyzed by the Doctor.

Category

Treatment - Drugs

2

Description

Control group: In the Control group, 2% Minoxidil, a Product of Pak Darou Company, will be used Once daily. 2% minoxidil will be applied once every Night in an Amount of 1 cc in a Pre-determined Area of 1 cm in Diameter. The Intervention Period is 24 weeks, and Imaging is performed at times Zero, 12 weeks, and 24 weeks after the Start of the Intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pharmaceutical Research Center - Sinai Hospital

Full name of responsible person

Mahsa Farshidi

Street address

Sina Hospital , Hafez Ave. / Pharmaceutical Research Center , Golgasht Blvd.

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Farshidimahsa8@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr, Parviz Shahabi

Street address

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Email

info@tbzmed.ac.ir

Web page address

https://www.tbzmed.ac.ir/

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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahsa Farshidi

Position

pharmacy student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mahsa Farshidi

Position

Student of pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available