Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Safety and efficacy of "GernaHair Premium" supplement on Telogen Effluvium hair loss: A triple-blind, randomized, placebo-controlled clinical trial

Protocol summary

Study aim
Evaluating the effectiveness and safety of oral capsules "Gernahair" in preventing hair loss, increasing hair growth and strength, and improving nail parameters in telogen effluvium patients

Design
A randomized, triple-blind, placebo-controlled clinical trial with a parallel group conducted on 57 patients

Settings and conduct
The study is conducted on telogen effluvium patients in Razi Hospital. The patients are randomly divided into 3 parallel groups. The patient, the dermatologist and the data analyst are unaware of the treatment type. All three groups of patients use supplements with the same packaging. Hair loss reduction, hair growth and strength, and nail quality are assessed during 3 visits in 0-3-6 months.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with female pattern hair loss Ludwig type II or I, Diffuse hair loss, Changes in hair structure, and nail growth disorders Exclusion Criteria: Symptomatic diffuse alopecia, FPHL Ludwig type III, androgenic alopecia, alopecia areata

Intervention groups
The first group receives 3 capsules of Gernahair Premium daily, the second group receives 1 capsule, and the third group receives 3 placebo capsules for 6 months. This supplement contains 30 mg thiamine,60 mg calcium pantothenate, 100 mg medicinal yeast, 20 mg L-cystine, 20 mg keratin, and 20 mg PABA per 1 capsule and the placebo contains microcrystalline cellulose.

Main outcome variables
Anagen hair rate, hair count, density, and cumulative hair shaft diameter, in the beginning, and after 3 and 6 months of treatment The patient's overall satisfaction with the treatment rating from 0 to 100

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240218061044N1**
Registration date: **2024-04-29, 1403/02/10**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-29, 1403/02/10**
Update count: **0**

Registration date
2024-04-29, 1403/02/10

Registrant information

Name
Maryam Nasimi

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-20, 1403/02/01

Expected recruitment end date
2024-07-22, 1403/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety and efficacy of "GernaHair Premium" supplement on Telogen Effluvium hair loss: A triple-blind, randomized, placebo-controlled clinical trial

Public title
Efficacy and safety of GernaHair Premium on hair loss

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with a history of hair loss who had clinical findings of female pattern hair loss (FPHL) Ludwig type II or I and parietal center telogen hair rate of more than 20%, as determined by TrichoScan Patients with diffuse hair loss without any evidence of underlying disease in medical history Patients with acquired or age-related damage to the hair structure, including thinning, brittle, or split end hair Patients with nail growth disorders such as soft or brittle nails with no evidence of underlying disease in the medical history

Exclusion criteria:
Symptomatic diffuse alopecia (eg, due to iron deficiency or thyroid disorder) FPHL Ludwig type III Androgenic alopecia with or without virile symptoms as a result of polycystic ovaries, late-onset adrenogenital syndrome and ovarian, adrenal, or pituitary tumors Systemic autoimmune diseases Debilitating diseases (eg, AIDS or malignancy) Alopecia Areata Inflammatory ulcer or other ulcerative alopecia Other inflammatory conditions affecting the scalp (such as seborrheic dermatitis, psoriasis, or contact dermatitis) Receiving any treatment for hair loss or participating in another clinical trial for 3 months before entering the study Receiving medications that may cause hair loss (such as anticoagulants, lipid-lowering drugs, retinoids, antiepileptic drugs, antithyroid drugs, androgens, progesterones with androgenic or relative toxic effects, Angiotensin Converting Enzyme inhibitors(ACE)) within 3 months before entering the study. Receiving drugs containing sulfonamides (interference with PABA) Initiation or termination of hormone replacement therapy or hormonal contraception within 6 months before entering the study Any type of hormone replacement therapy or oral contraceptive containing progesterone with an androgenic effect (such as Norethisterone, Norgestrel, levonorgestrel, Linsternol or Tibolone) Pregnancy or breastfeeding Known sensitivity to any of components

Age
From **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **57**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the block randomization method, patients are divided into three groups A, B, and C, where group A receives 3 Geranahir daily, group B receives 1 Geranahir daily, and group C receives placebo. A random numbers table is used to prepare a random list. If the generated number is between 0 and 2, the patient receives group A treatment, if it is between 3 and 5, the patient receives group B treatment, and if it is between 6 and 8, the patient receives placebo. According to the output of the Random Allocation Software, each patient has a special code that Determines which medicine they receive.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Gernahair premium boxes, one group of which contains the active substance and the other one contains the placebo, are prepared in a completely similar way to each other, and are randomly delivered to patients. The patient, the dermatologist, and the data analyzer are unaware of the type of treatment they are receiving also, the participants are unaware of the presence of other study groups and do not know that the number of GernaHair received in one day is different for every group.

Placebo
Used

Assignment
Parallel

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
Central Administration Building, University of Tehran, Qods Ave., Keshavarz Blvd

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Tehran

Province
Tehran

Postal code
1417653761

Approval date
2024-02-04, 1402/11/15

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.625

Health conditions studied

1

Description of health condition studied
Telogen Effluvium
ICD-10 code
L65.0
ICD-10 code description
Telogen effluvium

Primary outcomes

1

Description
Anagen hair rate
Timepoint
Before treatment, after 3 and 6 months of treatment
Method of measurement
Measuring the anagen hair rate in an area equal to 1.8 square centimeters in the center of the parietal of the scalp, while imaging the specific area and using the Trichoscan software

2

Description
Hair count
Timepoint
Before treatment, after 3 and 6 months of treatment
Method of measurement
Measuring the hair count in an area equal to 1.8 square centimeters in the center of the parietal of the scalp, while imaging the specific area and using the Trichoscan software

3

Description
Hair density
Timepoint
Before treatment, after 3 and 6 months of treatment
Method of measurement
Measuring the hair density in an area equal to 1.8 square centimeters in the center of the parietal of the scalp, while imaging the specific area and using the Trichoscan software

4

Description
Cumulative hair shaft diameter
Timepoint
Before treatment, after 3 and 6 months of treatment
Method of measurement
Measuring the cumulative hair shaft diameter in an area equal to 1.8 square centimeters in the center of the parietal of the scalp, while imaging the specific area and using the Trichoscan software

Secondary outcomes

1

Description
Participant's satisfaction with treatment
Timepoint
Before treatment, after 3 and 6 months of treatment
Method of measurement
The patient's overall satisfaction with the treatment will be evaluated from 0 to 100 so that 0 is a sign of absolute dissatisfaction and 100 is a sign of maximum consumer satisfaction.

Intervention groups

1

Description
Intervention group number 1: This group will take 3 Gernahair Premium capsules orally for 6 months. This supplement contains 90 mg thiamine, 180 mg calcium pantothenate, 300 mg medicinal yeast, 60 mg L-cystine, 60 mg keratin, and 60 mg PABA per 3 capsules.
Category
Treatment - Other

2

Description
Intervention group number 2 : This group will take 1 Gernahair Premium capsules orally for 6 months. This supplement contains 30 mg thiamine, 60 mg calcium pantothenate, 100 mg medicinal yeast, 20 mg L-cystine, 20 mg keratin, and 20 mg PABA per 1 capsules.
Category
Treatment - Other

3

Description
Control group: This group will receive 3 placebo capsules daily for 6 months that contain microcrystalline cellulose.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Maryam nasimi
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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?
No
Title of funding source
Tose-e Teb Adrian Salamat co.
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
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Maryam Nasimi
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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