

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5561 8989

##### Email address

m-nasimi@sina.tums.ac.ir

##### 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

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

**City**

Tehran

**Province**

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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

#### Street address

Razi Hospital , Vahdate-e-eslami St , Tehran , Iran

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
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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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Maryam Nasimi  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology

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## Person responsible for scientific inquiries

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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