

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Formulation, physicochemical characterization and single-group phase II clinical trial with comparison before and after treatment to evaluate the efficacy and clinical safety of 5% phenytoin solution in improving androgenic hair loss

Protocol summary

Study aim

Measuring the effectiveness and clinical safety of 5% phenytoin solution in improving androgenic hair loss

Design

Single-group phase II clinical trial comparing before and after on 15 patients

Settings and conduct

The patient must go to the skin clinic of Rasool Hospital on the first day, the second month and the fourth month. On the first day, he will be visited by the study researcher and he will provide the study researcher with information such as underlying diseases and medications. In the following, if he meets all the entry criteria, he will be included in the study. Also, in this visit, a photograph is taken of a certain area of the head and sampling is done from three areas of the head (forty hairs). At the end of the first visit, the study drug will be prescribed and the method of use and possible side effects will be explained by the researcher. In the visit of the second month and the fourth month, he was visited by the study researcher. Also, in these two visits, photographs were taken of a certain area of the head and sampling was done from three areas of the head (forty strands of hair) and the patient expressed his level of satisfaction with He informs his doctor about the treatment process and the resulting changes. Cooperation in this study lasts for four months, and during this period, the patient must visit the skin clinic of Rasool Hospital three times at intervals of two months. Each visit takes about 15 to 20 minutes.

Participants/Inclusion and exclusion criteria

A man aged between 18 and 50 years Hair loss pattern based on Hamilton Norwood scale (II, III, IV) Enjoying public health Sign the consent form

Intervention groups

Improvement of androgenic hair loss by use 5%

phenytoin solution twice a day.

Main outcome variables

The number of hairs in a specified area of the scalp

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190901044666N3**

Registration date: **2022-12-17, 1401/09/26**

Registration timing: **prospective**

Last update: **2022-12-17, 1401/09/26**

Update count: **0**

Registration date

2022-12-17, 1401/09/26

Registrant information

Name

Afsaneh Sadeghzadeh bazargan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2421

Email address

sadeghzadeh.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation, physicochemical characterization and single-group phase II clinical trial with comparison before and after treatment to evaluate the efficacy and clinical safety of 5% phenytoin solution in improving androgenic hair loss

Public title

The effect of 5% phenytoin solution in improving androgenic hair loss

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A man aged between 18 and 50 years Hair loss pattern based on Hamilton Norwood scale (II, III, IV) Sign the consent form Enjoying general health

Exclusion criteria:**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: **15**

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 Iran University of Medical Sciences, School of Medicine

Street address

School of Medicine, Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2022-12-05, 1401/09/14

Ethics committee reference number

IR.IUMS.REC.1401.682

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**

The number of hairs in a specified area of the scalp

Timepoint

At screening, 2 and 4 months after treatment

Method of measurement

ترجمه پیش از حد طولانی است و ذخیره نمی‌شود
In this examination, the area of the scalp is determined, and all examinations are performed on that area. The number of hairs at the beginning of the study, 2 months later and 4 months later is counted by the FotoFinder Tricoscale device. The tricoscale program from the FotoFinder device, a new program for documenting and quantifying hair loss, with the help of this software, all the basic parameters of hair growth and loss are calculated automatically. The parameters measured by this device are: calculating the number and density of hairs, the ratio and frequency of anagen and telogen hairs, the number and density of vulus and terminal hairs, determining hair thickness (optional), determining the number of follicular units. At the same time, the condition of the entire head hair is checked by a precision camera at the beginning of the study, 2 and 4 months after the treatment.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: treatment with 5% phenytoin solution twice a day for 4 months. For this purpose, the patient uses one milliliter of 5% phenytoin solution

topically on his scalp.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram hospital

Full name of responsible person

Afsaneh Sadeghzadeh bazargan

Street address

Rasool Akram hospital, Niayesh avenue, Sattarkhan street, Tehran, Iran

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sadeghzadeh.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran 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?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Sadeghzadeh bazargan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Sadeghzadeh bazargan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Contact

Name of organization / entity

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Full name of responsible person

Sina Maskoukian

Position

Pharm.D Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Email

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