

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Preparation and evaluation of topical solution of Cetirizine in prevention and treatment of Androgenetic Alopecia

Protocol summary

Study aim

Evaluate the efficacy of topical solution of cetirizine in prevention and treatment of androgenetic alopecia

Design

in this study 40 patients with mild to moderate androgenetic alopecia referring to the center of skin and leprosy are selected. participants are randomly in one of the two groups minoxidil or cetirizine .

Settings and conduct

the study conducted on all patients with mild to moderate androgenetic alopecia referred to the center of research and training in skin and leprosy .the study is randomized parallel single blind (patient) .patients in both treatment groups will use topical formulation with similar physical appearance and packaging.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male patients at the age of 18 to 49 years; Male pattern hair-loss should be at 2,3,4 in Norwood Scale; Signed informed consent voluntarily and knowingly; Exclusion criteria: History of allergy to Cetirizine or Minoxidil; Use of 5-alpha reductase inhibitor in the last year; Use of Isotretinoin over the past year; Use of nutritional supplement and herbal remedies for hair growth in the last 3 months; Chemotherapy in the last year; Scalp is exposed to radiation in the past year; History of uncontrolled Blood Pressure; History of Hypotension; Taking systemic Steroid for more than 14 days in the last 2 months.

Intervention groups

Intervention group: using cetirizine topical solution, twice a day in hair- loss areas for 4 months . Control group: using minoxidil topical solution, twice a day in hair- loss areas for 4 months.

Main outcome variables

hair count ; hair density

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161207031288N3**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-04, 1396/12/13**

Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

Saman Ahmad Nasrollahi

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 8190

Email address

snasrollahi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30

Expected recruitment end date

2018-07-05, 1397/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation and evaluation of topical solution of

Cetirizine in prevention and treatment of Androgenetic Alopecia

Public title

Effect of topical solution of Cetirizine on Androgenetic Alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Males st the age of 18 to 49 years Male pattern hair-loss should be at 2,3,4 in Norwood Scale Signed informed consent voluntarily and knowingly

Exclusion criteria:

History of allergy to Cetirizine or Minoxidil Using 5-alpha reductase inhibitor in the last year Using Isotretinoin over the past year Using nutritional supplement and herbal remedies for hair growth in the last 3 months Chemotherapy in the last year Scalp has been exposed to radiation in the past year History of uncontrolled Blood Pressure History of Hypotension Taking systemic Steroid for more than 14 days in the last 2 months

Age

From **18 years** old to **49 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

By using the random numbers table

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study patients are blind to the type of intervention they receive. Patients in both treatment groups will use topical formulation with similar physical appearance and packaging.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Pharmaceutical Sciences branch , Islamic Azad University

Street address

Pharmaceutical sciences branch , Islamic Azad University, Yakhchal street , Shariati street , Tehran

City

tehran

Province

Tehran

Postal code

193956466

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.IAU.PS.REC.1396.136

Health conditions studied

1

Description of health condition studied

Androgenetic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

hair count

Timepoint

Before intervention , two months later, 4 months later

Method of measurement

fotofinder trichoscale

2

Description

hair density

Timepoint

Before intervention , two months later, 4 months later

Method of measurement

fotofinder trichoscale

Secondary outcomes

1

Description

anagen -telogen hair percentage

Timepoint

Before intervention , two months later, 4 months later

Method of measurement

fotofinder trichoscale

2

Description

number and density of vellus hair to terminal hair

Timepoint

Before intervention , two months later, 4 months later

Method of measurement

fotofinder trichoscale

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

Intervention group: using Cetirizine topical solution, twice a day in hair- loss areas for 4 months.

Category

Treatment - Drugs

2**Description**

Control group: using minoxidil topical solution, twice a day in hair- loss areas for 4 months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Center of research and training in skin disease and leprosy

Full name of responsible person

Saman Ahmad Nasrollahi

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no.415 ; Taleghani Ave; Tehran

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1416613675

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Email

sammannasrol@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Center of research and training in skin diseases and leprosy

Full name of responsible person

Alireza Firouz

Street address

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Alifirouz@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Center of research and training in skin diseases and leprosy

Proportion provided by this source

50

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**

Islamic Azad University

Full name of responsible person

Delaram Hossein Mostafa

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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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