Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Isotretinion 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 Isotretinion 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 Hypotention 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 percantage
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
Street address
no.415 ; Taleghani Ave; Tehran
City
Tehran
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Postal code
1416613675
Phone
+98 21 8897 2220
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
no. 145 ;Taleghani ave; Tehran
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1416613675
Phone
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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 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