

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparing the effect of topical cetirizine versus topical minoxidil on hair growth in women with female pattern hairloss

Protocol summary

Study aim

Comparison the effect of topical cetirizine versus topical minoxidil on hair growth in women with female pattern hairloss

Design

Patients based on randomization software were divided into 2 groups each include 45 patient. and for 6 months they will be under treatment with topical cetirizine while the control group will be treated with topical minoxidil.

Settings and conduct

Patient is diagnosed by a dermatologist and by the use of randomization software patients were divided into 2 groups. tested group were given cetirizine 1% 1 ml to be used topically on the scalp. In the control group used a 2% minoxidil solution where 1 ml was used on the scalp. Patients were evaluated at the beginning 1st 3rd and 6th month of study the hair loss evaluation was based on shedding scale and Sinclair scale as well as thickness and number of hair unit via trichoscopy. If patient during 3rd month didn't show any response they will be omitted from the study. Otherwise they'll continue the use of the solution until the 6th month then re-evaluated by trichoscopy and then photographs will be taken then the data will be analyzed. Patients are who visited the dermatology clinic.

Participants/Inclusion and exclusion criteria

Female with female pattern hair loss without androgenetic hormonal imbalance disorders, Who did not undergo any treatment in regard to hair loss for the last 6 months, No other causes for hair loss such as inflammatory or scarring hair loss and also

Intervention groups

One group were given cetirizine 1% solution 1 ml to be used topically on the scalp. the other group used a 2% minoxidil solution where 1ml twice daily was used on the scalp. both for a period of 6 months.

Main outcome variables

Hair loss condition based on Sinclair scale and shedding scale Study of density and thickness of hair by

trichoscopy Measurement time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047536N1**

Registration date: **2021-01-05, 1399/10/16**

Registration timing: **retrospective**

Last update: **2021-01-05, 1399/10/16**

Update count: **0**

Registration date

2021-01-05, 1399/10/16

Registrant information

Name

Seyed mohammad kazem Alavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3291 1698

Email address

alavimk96@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of topical cetirizine versus topical minoxidil on hair growth in women with female pattern hairloss

Public title

The effect of topical cetirizine on hair growth in women with female pattern hairloss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female with female pattern hair loss without androgenetic hormonal imbalance disorders Who did not undergo any treatment in regard to hair loss for the last 6 months No other causes for hair loss such as inflammatory or scarring hair loss Consent for entering into the research

Exclusion criteria:

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple, this method use simple randomization models such as random number table or computerized randomization for example assign each participant to intervention group or control group by random number table. Allocation Concealment: A random number table using www.randomization.com A random number table is a large collection from numbers that does not have a regular pattern and completely randomized was made in a form of a table. 45 sets each has 2 patients one is named patient 1 and the other one is patient 2. In each set one Patient was given minoxidil and another patient was given cetirizine. Investigator randomly select patients and based on his or her number (1 or 2) the allocated medicine was given.

Blinding (investigator's opinion)

Double blinded

Blinding description

Individuals under study, evaluators and analysts will be unaware of the intervention and control groups. A 60 ml container without label filled with either minoxidil or cetirizine was given to the patients and they were unaware of its contents. Evaluators and analysts will be unaware that data is related to minoxidil group or cetirizine group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of mashad university of medical sciences

Street address

Opposite to Daneshgah 18 St, Mashhad University of Medical Sciences, Deputy of Research and Technology of the University

City

mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

ir.mums.medical.rec.1398.091

Health conditions studied

1

Description of health condition studied

female pattern androgenic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

situation of hair loss

Timepoint

at the beginning 1st 3rd and 6th month

Method of measurement

sinclair scale and shedding scale

2

Description

evaluation of hair density and hair thickness

Timepoint

at the beginning 1st 3rd and 6th month

Method of measurement

by tricoscopy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: topical solution of 1% cetirizine 1 ml daily for 6 month

Category

Treatment - Drugs

2

Description

Control group: topical solution of 2% minoxidil 1 ml twice daily for 6 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Imam Reza Hospital Hospital in Mashhad

Full name of responsible person

dr pouran layegh

Street address

The beginning of Daneshgah St, Mashhad, Imam Reza Hospital

City

mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 5726

Email

emamreza@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Opposite to Daneshgah 18 St, Mashhad University of Medical Sciences, Deputy of Research and Technology of the University

City

mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3841 2081

Email

vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Seyed mohammad kazem alavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 65. kafi15 Ave. tabarsi62 Ave. tabarsi St

City

mashhad

Province

Razavi Khorasan

Postal code

9157794739

Phone

+98 25 3291 1698

Email

Alavimk961@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr pouran layegh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Daneshgah st, Imam Reza hospital, Dermatology department

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51385430319

Email

Layeghpo@mums.ac.ir

+98 25 3291 1698

Email

Alavimk961@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

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

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Mohammad Kazem Alavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 65. kafi15 Ave. Tabarsi 62 Ave. Tabarsi St

City

Mashhad

Province

Razavi Khorasan

Postal code

9157794739

Phone