

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of the effects of combination of topical minoxidil, biotin in comparison with topical minoxidil on mild to moderate androgenetic alopecia patients referring to dermatological clinics of Alzahra hospital

Protocol summary

Study aim

Find a topical drug for androgenetic alopecia that is more effective than the approved minoxidil drug.

Design

Clinical trial, with parallel groups, triple blind, randomized, sample size of 40 people, randomization with online randomization

Settings and conduct

This study is a triple blind randomized clinical trial performed at Al-Zahra Hospital in Isfahan. In this study, patients whose diagnosis has been clinically proven and who meet the inclusion criteria are reviewed and randomly divided into two groups. Before starting the treatment, the patients fill in the form related to the patient information and a standard photo is taken in each patient and the number of patients' hair in a specific area of the scalp is counted by a hair polarizer.

Participants/Inclusion and exclusion criteria

Patients who wish to participate in the study. Patients with androgenetic alopecia. Patients who have not been treated with finasteride or other anti-androgen therapy for the past 6 months.

Intervention groups

In the intervention group, the combination of minoxidil and biotin is used topically and in the control group, minoxidil alone is used.

Main outcome variables

Number of hairs; standard photographic score; hair regrowth score from patients' point of view; duration of disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200811048371N1**

Registration date: **2020-11-17, 1399/08/27**

Registration timing: **retrospective**

Last update: **2020-11-17, 1399/08/27**

Update count: **0**

Registration date

2020-11-17, 1399/08/27

Registrant information

Name

Fatemeh Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-15, 1399/04/25

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effects of combination of topical minoxidil, biotin in comparison with topical minoxidil on mild to moderate androgenetic alopecia patients referring to dermatological clinics of Alzahra hospital

Public title

Assessment of the effects of combination of topical minoxidil, biotin in comparison with topical minoxidil on mild to moderate androgenetic alopecia patients referring to dermatological clinics of Alzahra hospita

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with androgenetic alopecia Patients who have not been treated with finasteride or other anti-androgen therapy for the past 6 months

Exclusion criteria:

Patients with other types of alopecia (such as alopecia areata, telogen effluvium, anagen effluvium, and scarring alopecia) Receiving systemic treatment for androgenetic alopecia during the last 6 months History of allergy to minoxidil, biotin

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients in whom the inclusion criteria apply are unlikely and easy to enter the study and the treatment is assigned to the two groups randomly with the help of online randomization. The first group of patients treated with topical minoxidil alone and the other group of patients receiving a combination of minoxidil and biotin. How to blind: Drugs in the same boxes with the same volume are given to a nurse outside the group and are coded in A and B, and the patient and the evaluating physician are unaware of the type of codes. The data is analyzed in the form of coding, so the analyst is unaware of their allocation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The medicines are given to an out-of-group nurse in the same boxes with the same volume and are coded in A and B forms, and the patient and the evaluating physician are unaware of the type of codes. The data is analyzed in the form of coding, so the analyst is unaware of their allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Science

Street address

Isfahan University of Medical sciences, Hezarjarib Blvd.

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Isfahan

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8174673461

Approval date

2020-07-30, 1399/05/09

Ethics committee reference number

IR.MUI.MED.REC.1399.353

Health conditions studied

1

Description of health condition studied

Androgenetic alopecia

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

Primary outcomes

1

Description

Standard photographic score (reported by physician)

Timepoint

The effect of these two classes of drugs is measured at the end of week 24

Method of measurement

Physician evaluation of hair regrowth at the end of week 24: In this method, a physician who is blind to the study by comparing pre- and post-treatment photographs (taken by Standardized global photography in 4 views) according to a 7- point scale gives points (14). Given that all patients are examined by a physician, the probability of error in subjective assessment is low. Greatly decreased = -3 Moderately decreased = -2 Slightly decreased = -1 No change = 0 Slightly increased = +1 Moderately increased = +2 Greatly increased = +3

2

Description

Hair regrowth score from patients' point of view

Timepoint

The effect of these two classes of drugs is measured at the end of week 24

Method of measurement

Evaluate the patient for hair regrowth at the end of week 24: In this method, the patient scores according to a 7-point scale: Greatly decreased = -3 Moderately decreased = -2 Slightly decreased = -1 No change = 0 Slightly increased = +1 Moderately increased = +2 Greatly increased = +3

3

Description

number of hair

Timepoint

The effect of these two classes of drugs is measured at the end of week 24

Method of measurement

Hair count at the end of week 24 and comparison with the number of hairs at the beginning of the study: The results will be obtained through the hair polarizer (KC Technology).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The combination of minoxidil and biotin in a cc twice a day, due to the fact that minoxidil is dissolved in an alcoholic solvent and biotin in an aqueous solvent, to make a solvent system of 60% alcohol, 10% propylene glycol, 1% lactic acid and approximately 30% water is used. Minoxidil 5% at a rate of 1 ml and biotin at 5 mg / dl at a rate of 2 ml.

Category

Treatment - Drugs

2

Description

Control group: Using topical minoxidil as one cc twice a day, 60% alcohol, 10% propylene glycol, 1% lactic acid and approximately 30% water are used to make the solvent system. Minoxidil 5% is used in the amount of 1 ml.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Esfahan Alzahra Hospital

Full name of responsible person

Fatemeh Mokhtari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Mokhtari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Latest degree

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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