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)

Phone
+98 31 3629 4542

Email address
f_mokhtari2004@yahoo.com

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 Universiy of Medical sciences, Hezarjarib Blvd.

City
Esfahan

Province
Isfehan

Postal code
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 = -3Moderately decreased = -2Slightly decreased = -1No change = 0Slightly increased = +1Moderately increased = +2Greatly 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 = -3Moderately decreased = -2Slightly decreased = -1No change = 0Slightly increased = + 1Moderately increased = + 2Greatly 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

Street address

Alzahra Hospital, Sofeh Blvd., Isfahan

City

esfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3629 4542

Email

f_mokhtari2004@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghju Javanmard

Street address

Isfahan University of Medical Sciences, Hezarjarib Blvd

City

Esfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

sh_haghjoo@med.mui.ac.ir

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

Street address

Isfahan Uiversity of Medical Sciences, Hezarjarib Blvd., Isfahan

City

Esfahan

Province

Isfehan

Postal code

7346181746

Phone

+98 31 3629 4542

Email

f_mokhtari2004@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Mokhtari

Position

Associate professor

Latest degree

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Phone

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Email

f_mokhtari2004@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Mokhtari

Position

Associate professor

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Street address

Isfahan University of Medical Sciences, Hezarjarib Blvd., Isfahan

City

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Province

Isfehan

Postal code

7346181746

Phone

+98 31 3629 4542

Fax

Email

f_mokhtari2004@yahoo.com

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