

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the Efficacy of Topical Herbal Solution on the Treatment of Androgenetic Alopecia and Comparison with Minoxidil 5%: A Double-Blind, Randomized, Clinical Trial Study

Protocol summary

Study aim

Effect of topical plant solution on prevention and treatment of androgenic hair loss and comparison with minoxidil 5%

Design

This study is done on male patients with androgenic hair loss. The patients will be selected by volunteers attending Dermatology department of Sina Hospital and eligible individuals will be selected among them. The participants will be randomly allocated (using random number tables) to two groups, plant solution or minoxidil. Sample size will be 40 patients.

Settings and conduct

This study will be conducted on patients aged 18 to 50 years old with mild to moderate androgenic hair loss in the department of Sina Hospital. They will be randomly divided into 2 groups, and the patient and doctor will be unaware of the type of received treatment. Both groups will use the same package of medications.

Participants/Inclusion and exclusion criteria

Entry requirements include 18 to 50-year-olds who are clinically diagnosed with Hamilton's criteria for grade 3 to 5 androgenetic alopecia, have a normal general health condition and have written consent. Exclusion criteria include the use of any local herbal remedy for hair loss in the past 3 months, chemotherapy and anti-inflammatory drugs and 5-alfa reductase drugs in the past 1 year, systemic steroid in past 14 days, uncontrolled hypertension, any chronic inflammation or infection in Scalp, people with hormonal diseases such as thyroid disorders, diabetes, liver disease, kidney, cancer, people without written consent and smokers.

Intervention groups

Intervention group: Use of minoxidil solution in the morning and herbal solution at night, every day in hair loss areas for 3 to 6 months Control group: Use minoxidil solution every day in hair loss areas for 3 to 6 months

Main outcome variables

Number of hair; hair thickness;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181103041541N1**

Registration date: **2019-02-16, 1397/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-15, 1398/04/24**

Update count: **1**

Registration date

2019-02-16, 1397/11/27

Registrant information

Name

Farid Masoud

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3362 0084

Email address

faridmasoud@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-28, 1397/09/07

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the Efficacy of Topical Herbal Solution on the Treatment of Androgenetic Alopecia and Comparison with Minoxidil 5%: A Double-Blind, Randomized, Clinical Trial Study

Public title
Effect of topical plant solution on male hair loss

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Men 18 to 50 years old Written consent General health status is normal Hamilton's 2 to 5 degree hair loss
Exclusion criteria:
Use of any topical product for hair loss in the last 3 months Use of chemotherapy drugs and anti-inflammatory drugs and 5-alfa reductase drugs in the past 1 year Uncontrolled hypertension Any chronic inflammation or infection in the scalp Hormonal diseases such as thyroid disorders, diabetes and ... Smokers Liver and kidney disease No written consent

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

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
A computer-generated list of random numbers was used. The randomization sequence was created using Stata 9.0 statistical software and was stratified by center with a 1:1 allocation using random block sizes of 2, 4, and 6

Blinding (investigator's opinion)
Double blinded

Blinding description
Both groups of patients use the same package. The Doctor and the patient are unaware of the type of used drug .

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
مرکز ثبت کارآزمایی بالینی آمریکا

Secondary trial Id
NCT03753113

Registration date
2018-11-26, 1397/09/05

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Daneshgah Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165687386

Approval date
2018-08-06, 1397/05/15

Ethics committee reference number
IR.TBZMED.REC.1397.384

Health conditions studied

1

Description of health condition studied
Androgenic Alopecia

ICD-10 code
L64

ICD-10 code description
Androgenic alopecia

Primary outcomes

1

Description
Number of hair

Timepoint
Before intervention, 2 months later, 4 or 6 months later

Method of measurement
Global photograph of a patient

2

Description
Hair thickness

Timepoint
Before intervention, 2 months later, 4 or 6 months later

Method of measurement
Fotofinder trichoscale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use of minoxidil solution in the morning and herbal solution at night, every day in hair loss areas for 3 to 6 months

Category

Treatment - Drugs

2

Description

Control group: Use minoxidil solution every day in hair loss areas for 3 to 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Dermatology, Sina Hospital

Full name of responsible person

Hameedeh Azimi Alamdari

Street address

Between Montazeri and Hafez, Azadi street

City

Tabriz

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East Azarbaijan

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Phone

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Email

info@sinahosp.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hossein Babaei

Street address

Drug Applied Research Center Medical Research and Development Complex Daneshgah St.

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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

Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Farid Masoud

Position

Pharmacy Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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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