Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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
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Tabriz
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1111111111
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Email
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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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Phone
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Email
info@darc.tbzmed.ac.ir
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
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Farid Masoud
Position
Pharmacy Student
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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