Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the effect of oral product containing Amla fruit (Phyllanthus emblica L.) on women’s androgenic alopecia: a Randomized Controlled Clinical Trial.

Protocol summary

Study aim
Evaluation of the effect of an oral product containing Amla fruit on women's androgenic alopecia

Design
A paralleled-triple-blinded randomized clinical trial with 30 cases in each two study groups

Settings and conduct
This study will be conducted on eligible patients referred to Dermatology and Leprosy Research and Training Research Center. After finding eligible cases, explaining the study goals, and taking a written consent form, all participants will be assigned to two study groups, intervention, and control, using a random allocation method. In the following, after registering subject identifications, similar pockets containing the drug or placebo will be given to each group. Researchers, volunteers, outcome assessors, and statistical data analysts do not have any information about drugs and placebo groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women aged 18 to 60 years old, type 1 to 2 hair loss according to the Hamilton Hair Loss Criterion that has lasted more than six months, and patient's consent to participate in the study; Exclusion criteria: records of using any typical products to prevent hair loss or stimulate hair growth, using 5 α reductase inhibitors, using anti-androgenic drugs, systemic steroid treatments, any active diseases in the head including scalp infection, any records of acute illness, history of any cancer or autoimmune diseases, undertaking hair transplantation, having chronic diabetes, hypothyroidism, polycystic ovary syndrome, pregnancy, and lactation.

Intervention groups
Each eligible patient will take 30 ml (10 ml syrup after each meal) of medicine or placebo daily for 12 weeks.

Main outcome variables
Number of hair strands; Terminal hairs to Volos; Ratio of anagen to telogen hair; Physician satisfaction with treatment; Patient satisfaction of treatment

General information

Reason for update
Record the end of the trial

Acronym

IRCT registration information
IRCT registration number: **IRCT20201010048979N2**
Registration date: **2021-10-27, 1400/08/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-23, 1401/12/04**
Update count: **1**

Registration date
2021-10-27, 1400/08/05

Registrant information

Name
Marzieh Akhbari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-16, 1400/07/24

Expected recruitment end date
2022-03-15, 1400/12/24

Actual recruitment start date

2021-09-29, 1400/07/07

Actual recruitment end date

2022-02-19, 1400/11/30

Trial completion date

2022-02-19, 1400/11/30

Scientific title

Evaluation of the effect of oral product containing Amla fruit (Phyllanthus emblica L.) on women’s androgenic alopecia: a Randomized Controlled Clinical Trial.

Public title

The effect of oral product containing amla fruit on women’s androgenic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 to 60 years old Type 1 to 2 hair loss according to the Hamilton Hair Loss Criterion that has lasted more than 6 months Patient consent approval to participate in the study

Exclusion criteria:

Records of using any typical products to prevent hair loss or stimulate hair growth in the past 2 months Utilizing 5 α reductase inhibitors in the past 2 months Records of taking anti-androgenic drugs in the past 2 months Records of systemically taken steroids for more than 14 days in the past 2 months Any active diseases in the head including scalp infection in the past 6 months Records of any types of cancer or autoimmune diseases Any records of hair transplantation Pregnancy and lactation The history of underlying diseases of diabetes, hypothyroidism, polycystic ovary syndrome The history of acute illness in the last 2 months

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

The study group will be randomly divided into two groups of medicine and placebo. Due to patients' gradual referral and maintaining balance in groups, individuals are randomly selected by permuted block randomization with quadruple blocks. Thus, according to the table of random numbers, four samples of one of the blocks with the sequence; BAAB, BABA, BBAA AABB, BAAB, ABAB are selected. Letter A means assigning a person to the intervention group, and letter B means assigning a person to the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The medicine and the placebo are the same in appearance and packaging. They can be distinguished only by the unique codes inserted by the pharmacist on the medicine bottle's label. The patient and the researcher prescribing and analyzing the data are not aware of the meaning of the codes. The study results are also reviewed by a researcher who is unaware of the grouping and is blind to the groups and the type of drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

1th Floor, Medicine School, Poursina St, Qods St, Enghelab St.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-07-03, 1400/04/12

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.414

Health conditions studied

1

Description of health condition studied

Androgenic alopecia

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

Primary outcomes

1

Description

Number of hair strands

Timepoint
Before intervention, 12 weeks after the intervention
Method of measurement
Trichoscan

2

Description
Terminal hair to Volos hair
Timepoint
Before intervention, 12 weeks after the intervention
Method of measurement
Trichoscan

3

Description
Ratio of anagen to telogen hair
Timepoint
Before intervention, 12 weeks after the intervention
Method of measurement
Trichoscan

4

Description
Physician satisfaction with treatment
Timepoint
Before intervention, 6 and 12 weeks after the intervention
Method of measurement
questionnaire

5

Description
Patient satisfaction with treatment
Timepoint
Before intervention, 6 and 12 weeks after the intervention
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Each eligible patient will take 30 cc of medication (10 cc of amla syrup after each meal) daily for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: Each eligible patient will take 30 cc (10 cc syrup after each meal) of placebo daily for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for Research and Training in Skin Diseases and Leprosy
Full name of responsible person
Marzieh Akhbari
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Center for Research and Training in Skin Diseases and Leprosy, N.79, Taleghani Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
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Position
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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
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
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
Title and more details about the data/document
The data from primary and secondary outcomes of patients will be available on supplementary files of published paper
When the data will become available and for how long
Available after publishing results
To whom data/document is available
All academic people
Under which criteria data/document could be used
It has not been made a decision yet.
From where data/document is obtainable
The person responsible for general accountability
What processes are involved for a request to access data/document
It has not been made a decision yet.

Comments