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
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 AAB, 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

Street address
Center for Research and Training in Skin Diseases and Leprosy, N.79, Taleghani Ave.

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Tehran

Postal code
1416613675

Phone
+98 21 8896 0880

Email
mentalheal8981@gmail.com

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Leila Shirbeigi

Street address
No.27, School of Traditional Medicine, Sarparast St., Taleghani Ave.

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Province
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1416663361

Phone
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Email
l.shirbeigi@yahoo.com

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
Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Marzieh Akhbari
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Leila Shirbeigi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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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.