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 5α 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
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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
**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**
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**
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
Person responsible for general inquiries

Contact
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Full name of responsible person
Marzieh Akhbari
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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.