

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the Effect of Topical Lotion of Myrtus communis and Phyllanthus emblica on the Androgenic Alopecia in Women: A Clinical Trial Study

Protocol summary

Study aim

The effect of Topical Lotion of Myrtus communis and Phyllanthus emblica on the Androgenic Alopecia in Women

Design

Randomized clinical trial including 3 interventional and 1 control groups, and it is triple-blinded. Phase 3 with 120 cases, randomly included in the study using "R software" by statistics specialist.

Settings and conduct

Through Ahmadiyeh and Khark Salamatkadeh and under the observation of dermatologist the patients enter the study, then precise assessment will be done in the derma lab of the "Center for Research and Training in skin disease and Leprosy". Statistics specialist allocated randomized codes by "R software" to study groups so patients, investigator and analyzer are blinded (triple blinded).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female Subjects (18-60) falling hair loss who are not menopause. and give a written informed consent
Exclusion criteria: • History of allergic response/hypersensitivity to any ingredients and pharmaceutical products. • Medical history of thyroid disorder, diabetes mellitus, polycystic ovary syndrome • Medical treatment for hair problems, consuming drugs (such as Minoxidil, Finasteride, Platelet rich plasma or Biotin), 5 α -reductase inhibitors, corticosteroid therapy, antiandrogenic agents and laser therapy in the 2 months prior to the study • Any active scalp disease, cancer or autoimmune diseases, hair transplant, serious acute illness • Pregnancy or breast-feeding

Intervention groups

1) Myrtus communis and Phyllanthus emblica 2) Phyllanthus emblica 3) Myrtus communis 4) placebo

Main outcome variables

1. Trico scan assessment: Hair number; Hair density; Hair

diameter; anagen - telogen ratio 2. Patient satisfaction assessment (5 Likert): before and after study in all groups. 3. physician satisfaction assessment (5 Likert): before and after study about all patients in groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230808059082N1**

Registration date: **2024-02-24, 1402/12/05**

Registration timing: **prospective**

Last update: **2024-02-24, 1402/12/05**

Update count: **0**

Registration date

2024-02-24, 1402/12/05

Registrant information

Name

Farzaneh Maftoon

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2027-01-20, 1405/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effect of Topical Lotion of Myrtus communts and Phyllanthus emblica on the Androgenic Alopecia in Women: A Clinical Trial Study

Public title
Effect of Lotion of Myrtus communts and Phyllanthus emblica on the Androgenic Alopecia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Females in the pre-menopausal period complaining of hair loss Patient consent to participate and fill out the informed consent form.
Exclusion criteria:
History of allergic response/hypersensitivity to any ingredients and pharmaceutical products. History of thyroid disorder, diabetes mellitus, polycystic ovary syndrome Subjects under medical treatment for hair problems, consuming drugs (such as minoxidil, finasteride, platelet rich plasma or Biotin) and laser therapy in the 2 months prior to the study Subjects under medical treatment for hair problems with 5 α -reductase inhibitors. Subjects under medical treatment with antiandrogenic agents (such as spironolactone, cimetidine and cyproterone acetate) in the 2 months prior to the study Subjects consuming systemic corticosteroid therapy for more than 14 days in the 2 months prior to the study Any active scalp disease in the 6 months prior to the study Any history of cancer or autoimmune diseases History of hair transplant Pregnancy or Brest - feeding History of serious acute illness in the 2 months prior to the study

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: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly assigned treatments to the patients will be accomplished using R software by statistics specialist .Thus statistics specialist allocated randomized codes by "R software" to study groups so patients, investigator

and analyzer are blinded(triple blinded).

Blinding (investigator's opinion)
Triple blinded

Blinding description
Blinding: Patients, researchers and analysts will not be informed of the random assignment of groups until the end of the study. Coding and also the pharmaceutical packaging for all groups is uniform, and the contents of the containers are similar in terms of consistency and color. At the end of the study, the desired code for grouping, which is inserted on the drug package, will be decoded to match the information and analyze the data.

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

Headquarters Building, Ghods street corner, Keshavarz Blvd.

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Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-07-17, 1402/04/26

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.054

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

Hair count (number of hairs in 0.7 cm²)

Timepoint

Week 8, week 16

Method of measurement

Trichoscan method

2

Description

Hair density (number of hairs in cm²)

Timepoint

Week 8, week 16

Method of measurement

Trichoscan method

3

Description

Hair diameter

Timepoint

Week 8, week 16

Method of measurement

Trichoscan method

4

Description

ratio of anagen to telogen

Timepoint

week8, week16

Method of measurement

Trichoscan method

Secondary outcomes

1

Description

Dandruff

Timepoint

Before and after study (week1, week16)

Method of measurement

Patient view assessment (5 Likert)

2

Description

Greasy hair

Timepoint

Before and after study (week1, week16)

Method of measurement

Patient view assessment(5 Likert)

Intervention groups

1

Description

Intervention groups: 4 including group 1: Iranian traditional medicine lotion based on Mirtica, group 2: traditional medicine lotion based on Amla, group 3: herbal product lotion based on the combination of Mirtica and Amla, and finally group 4: placebo lotion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahmadiéh Salamatkadeh

Full name of responsible person

Farzaneh Maftoon

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Ahmadiéh salamtkađeh, Sarparast str., Talaghani str.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Farzaneh Maftoon

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Others

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Other areas of specialty/work

Others

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Province

Tehran

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

For ethical reasons

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available