Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim

The effect of Topical Lotion of Myrtus communts 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 Ahmadieh 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, poly cystic 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 communts and Phyllanthus emblica 2) Phyllanthus emblica 3) Myrtus communts 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 (5Likert): 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)

Phone

+98 21 8806 1291

Email address

fmaftoon5@gmail.com

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.

City

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
Ahmadieh Salamatkadeh
Full name of responsible person
Farzaneh Maftoon
Street address
Ahmadieh salamtkadeh, Sarparast str.,Talaghani str.
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8897 4535
Email
spm@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbari Sari
Street address
Headquarters Building of Tehran University of Medical science, Ghods street corner, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3619
Email
research@tums.ac.ir
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
Farzaneh Maftoon
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Others
Street address
Ahmadieh salamtkadeh, Sarparast str.,Talaghani str.
City
Tehran
Province
Tehran
Postal code
1417613151´
Phone
+98 912 326 2644
Email
fmaftoon5@gmail.com

Person responsible for scientific 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
Street address
Ahmadieh salamtkadeh, Sarparast str.,Talaghani str.
City
Tehran
Province
Tehran
Postal code
1417613151´
Phone
+98 912 326 2644
Email
fmaftoon5@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Meysam Shirzad
Position
Scientific Member
Latest degree
Specialist
Other areas of specialty/work
Traditional Medicine
Street address
Ahmadieh salamtkadeh, Sarparast str.,Talaghani str.
City
Tehran
Province
Tehran
Postal code
1417613151´
Phone
+98 912 317 1481
Fax
Email
shirzadmd@gmail.com

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