Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Formulation and evaluation of topical product containing Myrtus communis L. and Phyllanthus emblica L . on hair loss based on iranian traditional medicine

Protocol summary

Study aim
The aim of this study is formulation and evaluation of topical product of myrtacea and phyllanthus on hair loss in human

Design
This study is randomized controlled pilot study to evaluate the effect of myrthus and pyllanthus on hair loss

Settings and conduct
The initial number of participants is 10 in each group which considering 10% dropout rate will be 20 in total and volunteers will be randomly assigned to the intervention and placebo groups

Participants/Inclusion and exclusion criteria
Woman participant age between 18 to 60 with complain of hair loss more than 6 months and non-entry criteria including woman with ovarian polycystic syndrome user of steroid and androgenic drugs hypothyroidism any hypersensitivity to any of ingredients of this product and G6PD deficiency

Intervention groups
Intervention group will use a traditional medicine gel containing leaves of myrthus and pyllanthus twice a day for 4 to 6 to 8 weeks and The control group will use a plain gel without herbal extract as a placebo, 15 drops, twice a day, for 6 to 8 weeks.

Main outcome variables
Rate of hair loss based on Likert'; hair loss base on comb test; patient satisfaction with treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240702062307N1**
Registration date: **2025-03-04, 1403/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-04, 1403/12/14**
Update count: **0**

Registration date
2025-03-04, 1403/12/14

Registrant information

Name
Armita Sabahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8842 2411

Email address
sabahi.armita@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-16, 1403/11/28

Expected recruitment end date
2025-03-18, 1403/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Formulation and evaluation of topical product containing Myrtus communis L. and Phyllanthus emblica L . on hair loss based on iranian traditional medicine

Public title
Formulation and evaluation of topical product containing

Myrtus communis L. and Phyllanthus emblica L . on hair loss based on iranian traditional medicine

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Woman age between 18 to 60 Hair loss complain more than 6 months

Exclusion criteria:
Any hypersensitivity to ingredients of gel Steroids users Any cancer History of hair transplantation Any deficient in g6pd enzyme Polycystic ovarian syndrome Androgenic drug user Hypothyroidsm

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
To divide people into two groups of 10 people, you can first randomly assign people from 1 to 20 numbers, then divide them into two groups using SAS 9.1 software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and researcher

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committees of Islamic Azad Medical Sciences, University of Pharmacy

Street address
Yakhchal street, Shariati street

City
Tehran

Province
Tehran

Postal code
1941933111

Approval date
2024-06-18, 1403/03/29

Ethics committee reference number
IR.IAU.PS.REC.1403.160

Health conditions studied

1

Description of health condition studied
Telogen effluvium

ICD-10 code
L65.0

ICD-10 code description
Telogen effluvium

Primary outcomes

1

Description
Satisfaction with hair loss, increased hair growth, and hair quality

Timepoint
Before the intervention, the first and fourth weeks after the start of the intervention

Method of measurement
By examining and questioning the patient and completing the Hamilton Hair Loss Questionnaire, the questionnaire assesses the level of satisfaction with hair loss before and after the intervention, as well as the level of satisfaction with the private status of hair loss, increased hair growth, and quality based on a five-point scale from very dissatisfied with a score of zero to very satisfied with a score of 5.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: The intervention group included 10 participants who received a placebo, which contained a simple gel without extract, administered twice daily, 15 drops of the desired gel each time, for 0, 4,8 weeks

Category
Treatment - Other

2

Description
Control group: The control group will use a simple gel without herbal extract as a placebo, 15 drops, twice a day, for 0, 4, and 8 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Institution of Traditional Medicine

Full name of responsible person
Ghazaleh Heydari Rad

Street address
Shahid Beheshti Institution of Traditional Medicine, Tavanir St., Vali Asr street

City
Tehran

Province
Tehran

Postal code
1996836111

Phone
+98 21 8877 3521

Email
dr.ghazalrad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Amirhossein Abdul Ghaffari

Street address
Yakhchal street, Shariati street

City
Tehran

Province
Tehran

Postal code
1941933111

Phone
+98 21 2263 3986

Email
maryamjahandideh2009@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
university

Proportion provided by this source
30

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
Islamic Azad University

Full name of responsible person
Armita Sabahi

Position
student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Islamic Azad University, Yakhchal street, Shariati street

City
Tehran

Province
Tehran

Postal code
1941933111

Phone
+98 21 8842 2411

Email
sabahi.armita@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Armita Sabahi

Position
student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Islamic Azad University, Yakhchal street, Shariati street

City
Tehran

Province
Tehran

Postal code
1941933111

Phone
+98 22633986

Email
sabahi.armita@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Aarmita Sabahi

Position
student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Islamic Azad University, Yakhchal street, Shariati street
City
Tehran
Province
Tehran
Postal code
1941933111
Phone
+98 21 2263 3986
Email
sabahi.armita@yahoo.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
no more information
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