Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of a product containing caffeine and rosemary essential oil (Rosmarinus officinalis) on reducing hair loss in patients with mild to moderate androgenetic alopecia

Protocol summary

Study aim
Investigating the effect of a product containing rosemary essential oil and caffeine on reducing hair loss in patients with mild to moderate androgenetic alopecia
Design
Clinical trial with parallel groups, without blinding, randomized, phase 3 on 60 patients, random permutation block method was used for randomization.
Settings and conduct
Patients will receive 1 CC of topical minoxidil 5% or product made of rosemary extract with caffeine, twice daily for men and once daily in women until 12 weeks in .
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Patients with androgenetic alopecia 2- Patients who want to participate in the study 3- Patients who are 15 to 45 years old. Exclusion criteria: 1- Patients with other types of alopecia 2- Patients with psoriasis or lichen planus 3- Patients with any serious systemic disease 4- Patients with photo-sensitivity 5- Patients with the history of hair transplant 6- Pregnant or Breast-feeding women 7- Patients with the history of ceffeine or rosemary sensitivity.
Intervention groups
Intervention group: Topical administration of product made of rosemary extract with caffeine. Control group: Topical administration of Minoxidil 5%
Main outcome variables
Hair density; hair thickness

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150221021159N10**
Registration date: **2024-08-12, 1403/05/22**
Registration timing: **prospective**
Last update: **2024-08-12, 1403/05/22**
Update count: **0**
Registration date
2024-08-12, 1403/05/22

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-09-22, 1403/07/01
Expected recruitment end date
2025-09-23, 1404/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of a product containing caffeine and rosemary essential oil (Rosmarinus officinalis) on reducing hair loss in patients with mild to moderate androgenetic alopecia

Public title
Investigating the effect of rosemary essential oil and

caffeine on reducing hair loss in patients with androgenetic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with mild to moderate androgenetic alopecia Patients who are between 15 and 45 years old. Patients who want to participate in the study and sign the informed consent form

Exclusion criteria:

Patients with other types of alopecia Patients with psoriasis or lichen planus Patients with serious systemic disease Patients with photosensitivity Patients with the history of hair transplant Pregnant or Breast-feeding women People with caffeine or rosemary allergy

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization with the permuted block method was used to create the random sequence in each group. At first, the specific internet software (https://www.sealedenvelope.com/simple-randomiser/v1/lists) was used to create the random series in blocks of 2, 4, and 6. Each block has an equal number of intervention and control groups. After that, created codes were written on the cards and placed respectively for hiding in locked opaque packets. A packet was selected for each patient according to the study recruitment, which determines the related study group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hazar Jarib Street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2024-03-19, 1402/12/29

Ethics committee reference number

IR.MUI.PHANUT.REC.1402.090

Health conditions studied

1

Description of health condition studied

Androgenetic alopecia

ICD-10 code

L64.8

ICD-10 code description

Other androgenic alopecia

Primary outcomes

1

Description

Hair regrowth rate

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of the study. Also, in case of desire and consent to continue the treatment after 24 weeks.

Method of measurement

Handy scope fotofinder Dermoscope device

Secondary outcomes

1

Description

Determination of density and thickness of hair

Timepoint

At the beginning of the study (before the start of the intervention) and 12 weeks after the start of the study. Also, in case of desire and consent to continue the treatment after 24 weeks.

Method of measurement

Handy scope fotofinder Dermoscope device

Intervention groups

1

Description

Intervention group: Intervention group: they are treated with the product made of onion and rosemary extract together with caffeine, twice a day. The duration of use is 12 weeks, but the treatment process in patients who

have the desire and consent to continue the treatment will continue for 24 weeks.

Category

Treatment - Drugs

2

Description

Control group: Control group: with topical minoxidil 5% in the form of one cc, twice a day for men and once a day for women. The duration of use is 12 weeks, but the treatment process in patients who have the desire and consent to continue the treatment will continue for 24 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
AL Zahra hospital
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Shadi Farsaei
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
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Isfahan university of medical sciences, Hezar jarib Avenue
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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

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Shadi Farsaei
Position
associate professor
Latest degree
Specialist
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Not applicable