

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Investigating the effect of a product containing onion extract, rosemary essential oil and caffeine on reducing hair loss in patients with mild to moderate androgenetic alopecia

Protocol summary

Study aim

Investigating the effect of a product containing onion extract, rosemary essential oil and caffeine on reducing hair loss in patients with mild to moderate androgenetic alopecia

Design

Clinical trial with parallel groups, 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 onion and 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 onion or rosemary sensitivity

Intervention groups

Intervention group: Topical administration of product made of onion and 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: **IRCT20150221021159N9**

Registration date: **2023-10-17, 1402/07/25**

Registration timing: **prospective**

Last update: **2023-10-17, 1402/07/25**

Update count: **0**

Registration date

2023-10-17, 1402/07/25

Registrant information

Name

Shadi Farsaei

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2618

Email address

farsaei@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of a product containing onion extract, rosemary essential oil and caffeine on reducing hair loss in patients with mild to moderate androgenetic

alopecia

Public title

Investigating the effect of onion extract and 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 onion and 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 Faculty of Pharmacy -Isfahan University of Medical Sciences - Hazar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-05-22, 1402/03/01

Ethics committee reference number

IR.MUI.MED.REC.1402.087

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

2

Description

Patient satisfaction

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: 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: 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

Full name of responsible person

Shadi Farsaei

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Soffeh Blvd.

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8174675731

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alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Isfahan university of medical sciences, Hezar jarib Avenue

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8148614481

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sh.farsaei@gmail.com

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

Other areas of specialty/work

Medical Pharmacy

Street address

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Title and more details about the data/document

There is no further information

When the data will become available and for how long

There is no further information

To whom data/document is available

There is no further information

Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

There is no further information

What processes are involved for a request to access data/document

There is no further information

Comments

There is no further information

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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