Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Isfehan
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

Street address
Soffeh Blvd.

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
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

City
Isfahan

Province
Isfehan

Postal code
8148614481

Phone
+98 913 325 3937

Email
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
Faculty of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Hazar Jarib St.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 7071

Email
Farsaei@pharm.mui.ac

Person responsible for scientific

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
Faculty of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Hazar Jarib St.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 7071

Email
Farsaei@pharm.mui.ac

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
Medical Pharmacy

Street address
Faculty of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Hazar Jarib St.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 7071

Email
Farsaei@pharm.mui.ac

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