Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Title : Clinical evaluation of the effect of the combination of herbal cream containing Rosmarinus officinalis, , Malva sylvestris, Foeniculum vulgare extract and Oenothera biennis and Bitter Almond Oil for treatment of hair loos on patients with Areata Alopecia

Protocol summary

Study aim
The purpose of using these plants is : combating for hair loss, increasing its regrowth by increasing blood circulation, providing nutrients for the activity of hair follicles and coming out of the resting stage.

Design
This research is a clinical double blind trail that 150 patients with the diagnosis of Alopecia areata referred to the Skin and Hair Clinic

Settings and conduct
Physician examination and survey by questionnaire

Participants/Inclusion and exclusion criteria
Inclusion: Suffering from total hair loss, alopecia in the head area, size of the lesion below 10 square centimeters, completing the consent form and agreeing to participate in the study, patients aged 18 to 60 years Exclusion: Patient unsatisfaction, pregnancy during the study, a lactating woman, universal alopecia areata, ophiiasis alopecia areata, sensitivity to triamcinolone, minoxidil or herbal combination before treatment, receiving oral or topical و Special patients, patients with migraine and epilepsy

Intervention groups
Men treated with minoxidil and herbal cream prepared daily and checked up by a doctor monthly - Women with alopecia areata (AA) who are treated with minoxidil and herbal cream prepared daily and checked-up by a doctor monthly Description Patients in case group received Glycyrrhiza glabra tablets, 2 tablets three times per day

Main outcome variables
The full growth in the empty file.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220818055740N3**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **retrospective**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date
2023-02-28, 1401/12/09

Registrant information

Name
Nahid Jivad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-07, 1397/07/15

Expected recruitment end date
2019-03-06, 1397/12/15

Actual recruitment start date
2018-10-07, 1397/07/15

Actual recruitment end date
2019-03-06, 1397/12/15

Trial completion date
2019-03-06, 1397/12/15

Scientific title
Title : Clinical evaluation of the effect of the combination

of herbal cream containing Rosmarinus officinalis, , Malva sylvestris, Foeniculum vulgare extract and Oenothera biennis and Bitter Almond Oil for treatment of hair loos on patients with Areata Alopecia

Public title

Title : Clinical evaluation of the effect of the combination of herbal cream containing Rosmarinus officinalis, , Malva sylvestris, Foeniculum vulgare extract and Oenothera biennis and Bitter Almond Oil for treatment of hair loos on patients with Areata Alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent for participation in the study hair loos on patients with Areata Alopecia

Exclusion criteria:

Having no satisfaction to participate in this study Having no suffering from hair loos on patients with Areata Alopecia

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **150**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were 150 patients and were selected by simple random sampling and Random assignment or random placement that is an experimental technique for assigning human participants or animal subjects to different groups in an experiment (e.g., a treatment group versus a control group) using randomization, such as by a chance procedure (e.g., flipping a coin). This ensures that each participant or subject has an equal chance of being placed in any group. Moreover, grouping of samples has been done using Randomizer(RA) software. Patients were divided into 6 groups of 25. For each treated group, a control group (triamcinolone cream) was placed separately, and the entrance of patients into these groups is random. Grouping of samples has been done using RA software. The blinding of this research is on behalf of the patient and the drug distributor. The homogenization of the studied groups is based on the variables: sex, age, type of alopecia areata and severity of hair loss in the head area. In general, randomization of patients was done based on coding.

Blinding (investigator's opinion)

Double blinded

Blinding description

The single blindness of the study was performed in this process that at first the mentioned drugs received code without any labels and the patient selected one of the two drugs randomly. Then, the name of each person and the drug code provided to him registered by the secretary. Neither the patient nor the doctor was not aware of the type of medication. The name of each person and his drug was specified only during analyzing the data, and completed the patients' information profile by mentioning the name of the drug received by them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord Univercity of Medical Sciences

Street address

Shahrekord - Kashani Street - Shahrekord Univercity of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

881571347

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

R.SKUMS.REC.1397.101

Health conditions studied

1

Description of health condition studied

Hair loss in patients with alopecia areata

ICD-10 code

(L80-L99)

ICD-10 code description

(L00-L99)

Primary outcomes

1

Description

Subjects under study are examined for the presence of hair loss in the target area (alopecia of the head area) based on the extent of loss (in cm2) and they are given a score from 0 to 10. The area of the lesion below 10 square centimeters is determined and at the end of every month after the visit by a specialist doctor, hairy and terminal regrowth (Based on its extent is checked by

examination, measurement (counting the number of hairs visually) and comparison with photography, as well as by surveying the patient.

Timepoint

Visit doctor monthly

Method of measurement

Physician examination and survey by questionnaire

Secondary outcomes

1

Description

Subjects under study are examined for the presence of hair loss in the target area (alopecia of the head area) based on the extent of loss (in cm2) and they are given a score from 0 to 10. The area of the lesion below 10 square centimeters is determined and at the end of every month after the visit by a specialist doctor, hairy and terminal regrowth (Based on its extent is checked by examination, measurement (counting the number of hairs visually) and comparison with photography, as well as by surveying the patient.

Timepoint

Monthly for 3 months

Method of measurement

Visit by doctor and survey by questionnaire

Intervention groups

1

Description

IMen treated with minoxidil and herbal cream prepared daily and checked up by a doctor monthly- Women with alopecia areata (AA) who are treated with minoxidil and herbal cream prepared daily and checked-up by a doctor monthly

Category

Treatment - Drugs

2

Description

- Men with alopecia areata (AA) treated with minoxidil daily and triamcinolone cream and checked-up by a doctor monthly (control group).- Men with alopecia areata (AA) who are treated with minoxidil and placebo (cream without ingredients) daily and checked-up by a doctor monthly.- Women with alopecia areata (AA) treated with minoxidil daily and triamcinolone cream and checked-up by a doctor monthly (control group).- Women with alopecia areata (AA) who are treated with minoxidil and placebo (cream without ingredients) daily and checked-up by a physician monthly

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
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Position
استاد

Latest degree
Ph.D.

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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
The project needs to complete.

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