

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effect of topical betamethasone, topical betamethasone with cryotherapy, topical betamethasone with cryotherapy and oral antihistamines on hair regrowth in alopecia areata patients

Protocol summary

Study aim

Evaluation of the effect of oral antihistamines in the treatment of alopecia areata patients and its comparison with conventional therapies.

Design

A randomized clinical trial with 48 patients in 3 groups of intervention

Settings and conduct

This study will be performed in dermatology clinics of Isfahan University of Medical Sciences. Patients with alopecia areata of the scalp or beard who are candidates for topical treatment are enrolled in the study. At first, the plan is explained to the patient and Written consent is obtained. Patient's information is recorded in special forms. The patients then randomly assigned to one of the three intervention groups. At the beginning and 3 months after the last session, patients' lesions are photographed and evaluated and scored by two neutral dermatologists who are unaware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with alopecia areata, at least 12 years old, with a maximum of three areas of hair loss, Exclusion criteria: Pregnant and lactating women, liver and kidney dysfunction, history of allergy to antihistamines and people with cold intolerance.

Intervention groups

Intervention group 1: Treatment with betamethasone 0.1% lotion. The patient uses one or two drops of the drug once a day (depending on the size of the bald area) for 12 weeks. Intervention group 2: Treatment with betamethasone 0.1% lotion similar to the first group and cryotherapy with liquid nitrogen which is used by a cotton swab on the hair loss area for 8 to 10 seconds for a maximum of six sessions at intervals of two weeks. Intervention group 3: Treatment with betamethasone 0.1% lotion and cryotherapy similar to the second group

plus des loratadine 5 mg tablets daily for 12 weeks. The tablets are made by Abidi Company.

Main outcome variables

Percentage of terminal hair regrowth; Patient satisfaction

General information

Reason for update

Since during the implementation of the study, we realized that there are patients who benefit from this treatment because of their special clinical situation, but due to the limitation of the diameter of the lesions, they are not able to enter the study, and considering that in previous similar studies, the maximum diameter of the lesions has been reported up to 7 cm, it was decided to consider the maximum diameter of the lesions as 3 x 3 cm in the inclusion criteria.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210404050843N1**

Registration date: **2021-05-14, 1400/02/24**

Registration timing: **prospective**

Last update: **2022-11-21, 1401/08/30**

Update count: **1**

Registration date

2021-05-14, 1400/02/24

Registrant information

Name

Marzieh sadat Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3772 0390

Email address

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2022-05-22, 1401/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of topical betamethasone, topical betamethasone with cryotherapy, topical betamethasone with cryotherapy and oral antihistamines on hair regrowth in alopecia areata patients

Public title
Effect of cryotherapy and oral antihistamine in treatment of Alopecia Areata

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patient age above 12 years Do not take another treatment for alopecia areata for at least one month before enrollment in this trial Maximum of three hair loss patches in the scalp or beard area, each of which is a maximum of 3 by 3 cm. No nail involvement related to alopecia areata

Exclusion criteria:
Renal or liver dysfunction Patients with a history of allergy to antihistamines Pregnancy or Lactation Lack of patient cooperation to complete the treatment process Cold intolerance Cryoglobulinemia History of cold urticaria

Age
From **12 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Three sets of 16 cards with the letters A, B and C written on them are prepared and placed in the bag, and each patient picks a card from the bag and their group is identified.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used
Assignment
Factorial
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

No 4, Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences, Hezar Jerib Blvd

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-03-20, 1399/12/30

Ethics committee reference number

IR.MUI.MED.REC.1399.1192

Health conditions studied

1

Description of health condition studied

Alopecia Areata

ICD-10 code

L63

ICD-10 code description

Alopecia areata

Primary outcomes

1

Description

Terminal hair regrowth percent

Timepoint

Before the intervention (at the beginning of the study) and three months after the last treatment session

Method of measurement

The evaluation is performed by the physician with the help of a questionnaire and based on the following scale:: Good response (more than 75% of terminal hair regrowth). Moderate response (between 50 and 75% of terminal hair regrowth). Poor response (between 25 to 50% of terminal hair regrowth) No response (less than 25% of terminal hair regrowth)

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

Before the intervention (at the beginning of the study) and three months after the last treatment session

Method of measurement

Patient satisfaction rate by the questionnaire based on numerical selection from one to ten (0= no effect, 1,2= minor effect, 3,4= moderate effect, 5,6= good effect, 9,10= very good effect)

Intervention groups

1

Description

Intervention group1: Treatment with betamethasone lotion 0.1%(made by Iran Najo company) daily for 12 weeks.The patient applies one to two drops of the drug (depending on the size of the bald area) once daily. This is repeated every day for 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: Treatment with betamethasone lotion 0.1%(made by Iran Najo company) daily for 12 weeks, similar to the first intervention group, and cryotherapy for a maximum of six sessions, every two weeks, for eight to ten seconds. Cryotherapy is done by liquid nitrogen available in dermatology clinic, with The cotton swab is held on the hair loss area for eight to ten seconds. Cryotherapy is repeated every two weeks until the desired result is achieved, but if no response is seen after six sessions, this treatment is discontinued.

Category

Treatment - Drugs

3

Description

Intervention group 3: Treatment with betamethasone lotion 0.1% (made by Iran Najo Company) daily for 12 weeks and cryotherapy for a maximum of six sessions every two weeks once each time eight to ten seconds similar to the second intervention group with des loratadine tablets 5 mg daily for 12 weeks. Des loratadine tablets made by Abidi Pharmaceutical Company. 90 units are prescribed for patients in this group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr. Majid Rezvani

Street address

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2

Recruitment center

Name of recruitment center

Sedigheh Tahereh Skin disease and Leishmaniasis Research Center

Full name of responsible person

Dr. Reza Etminani

Street address

Sedigheh Tahereh Skin disease and Leishmaniasis Research Center, Khorram Ave, Jomhoori Eslami Sq

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sdllrc@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

Street address

No.4,Vice-Chancellery for Research and Technology
Isfahan University of Medical Science, Hezar Jerib Blvd

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Web page address

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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

Marzieh Sadat Mousavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Full name of responsible person

Marzieh Sadat Mousavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

At the end of the study, study protocol, statistical analysis and clinical study report, the informed consent form, the codes used in the data analysis and the data dictionary can be shared with other researchers.

When the data will become available and for how long

Access period starts one month after the results are published

To whom data/document is available

Data will be available to researchers working in academic and scientific centers

Under which criteria data/document could be used

Researchers can use the findings and data of this study in their research by submitting a document that proves their employment in scientific and academic centers.

From where data/document is obtainable

Researchers can receive study data via sending an E-mail to researcher E-mail: marziehmusavi@gmail.com
phone number: 09134610431 Dr Marzieh sadat Mousavi
address: No1, Adl St, Mirzataher Ave, Isfahan, Iran

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

Researchers can send an email to the address to indicate the type of data they need, and after reviewing their request, the information will be sent to them via email.

Comments