Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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. Patinent's informations is recorded in special forms.The patients then randomly assigned to one of the three intervention groups. At the beginning and 3 month 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)

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+98 31 3772 0390

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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 Alopesia Areata
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patient age above 12 years Do not take another tratment 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
Isfehan
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
Sofe Blvd,Alzahra Hospital
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Email
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Web page address
http://alzahra.mui.ac.ir

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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Isfehan
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sdlrc@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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Email
research@mui.ac.i

Web page address
https://research.mui.ac.ir/

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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Contact

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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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