

# 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. 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

marziehmusavi1994@gmail.com

**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 desloratadine tablets 5 mg daily for 12 weeks. Desloratadine 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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

+98 31 3620 2020

##### Fax

+98 31 3669 1510

##### Email

alzahra@mui.ac.ir

##### 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

##### City

Isfahan

##### Province

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##### Postal code

8187698191

##### Phone

+98 31 3337 3736

##### Email

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

##### City

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##### Province

Isfahan

##### Postal code

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**Phone**

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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

**Street address**

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## Person responsible for scientific inquiries

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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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**Full name of responsible person**

Marzieh Sadat Mousavi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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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**