

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Efficacy of azelaic acid 20% versus anthralin 1% in patients with scalp alopecia areata

#### Protocol summary

##### Study aim

Efficacy of azelaic acid 20% and anthralin 1% In patients with alopecia areata

##### Design

Clinical trial, randomized, without blinding, with parallel groups on 60 patients

##### Settings and conduct

The present study will be performed in Sina Hospital in Tabriz. Patients will be randomly studied in two groups without blinding using a sealed eraser. Patients' recovery will be assessed. Patient recovery is defined as new hair growth that has a complete therapeutic response (above 90% of terminal hair), moderate (between 50% and 90% of terminal hair), low (between 10% and 50% of terminal hair) and no response (less than 10%). Terminal hair) will be evaluated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included alopecia areata scalp, failure to receive treatment during the previous month and consent to the study and exclusion criteria including pregnant women, receiving effective treatments for alopecia areata and corticosteroid and immunosuppressive and immunomodulatory drugs in Over the past month, Alopecia areata has been in a location other than the scalp and Alopecia areata Universalis and dissatisfaction with the study.

##### Intervention groups

In the group treated with 1% anthralin (dissolved in Vaseline), treatment will be started for 10 days. In order to cause mild inflammation, the duration of use will be increased by 10 minutes every 4 days. For patients who do not develop mild inflammation after 60 minutes, treatment will be considered overnight (for 8 hours). The group treated with 20% azelaic acid will be rubbed twice a day until they recover and for a maximum of 6 months in the areas of hair loss.

##### Main outcome variables

Patient recovery rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20091012002581N8**

Registration date: **2022-06-29, 1401/04/08**

Registration timing: **prospective**

Last update: **2022-06-29, 1401/04/08**

Update count: **0**

##### Registration date

2022-06-29, 1401/04/08

##### Registrant information

##### Name

Hamide Herizchi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1336 4650

##### Email address

herizchih@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-23, 1401/05/01

##### Expected recruitment end date

2022-09-22, 1401/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Efficacy of azelaic acid 20% versus anthralin 1% in patients with scalp alopecia areata

## Public title

Efficacy of azelaic acid 20% versus anthralin 1% in scalp alopecia areata

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having alopecia areata scalp Not receiving treatment during the previous month Consent for the study

### Exclusion criteria:

Pregnant women Receiving effective treatments for alopecia areata taking corticosteroids and immunosuppressants and immunomodulators during the past month Alopecia areata in a location other than the scalp and Alopecia areata universalis

## Age

No age limit

## 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 will be using sealed envelopes, of which 60 envelopes will be selected in total and will be divided into two groups of 30, including groups A and B.

## 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

Vice Chancellor for research of Tabriz University of Medical Sciences

##### Street address

Vice Chancellor for research, 3rd floor, central office, Tabriz University of Medical Sciences, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

## Postal code

515431232

## Approval date

2022-06-27, 1401/04/06

## Ethics committee reference number

IR.TBZMED.REC.1401.293

## 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

Patient recovery rate

#### Timepoint

Every month after intervention for 6 months

#### Method of measurement

Clinical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Anthralin 1% treatment group (dissolved in Vaseline) The treatment will start with the use for 10 minutes a day. In order to cause mild inflammation, the duration of use will be increased by 10 minutes every 4 days. For patients who do not develop mild inflammation after 60 minutes, treatment will be considered overnight (for 8 hours).

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: The group treated with 20% azelaic acid will be rubbed twice a day until they recover and for a maximum of 6 months in the areas of hair loss.

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Dr Hamideh Herizchi Ghadim

**Street address**

Azadi Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5163639888

**Phone**

+98 41 8236 3549

**Fax**

+98 41 8406 3549

**Email**

Drherizchi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Ataa Mahmoudpour

**Street address**

Azadi Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5163639888

**Phone**

+98 41 8236 3549

**Email**

Drherizchi@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Hamideh Herizchi Ghadim

**Position**

Dermatologist Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Dermatology ward, sina Hospital

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 1540 6612

**Fax****Email**

dr.herizchi@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Hamideh Herizchi Ghadim

**Position**

Dermatologist Assistant professor

**Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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dr.herizchi@yahoo.com

**Web page address****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**

No - There is not 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**

Study data is categorized and coded with no identifiable individuals.

**When the data will become available and for how long**

Access to study data after publication of the result is available in the journal.

**To whom data/document is available**

Anyone interested in using the data can access the study data.

**Under which criteria data/document could be used**

Study data can be used for comparison with other results.

**From where data/document is obtainable**

Refer to the study's scientific or public accountability person for data.

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

The request will be sent by email to person responsible for scientific or public inquiries.

**Comments**