

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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 updating data

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**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