Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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 Univercity of Medical Sciences

Street address
Vice Chancellor for research, 3rd floor, central office, Tabriz Univercity 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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
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Person responsible for updating data

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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
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