Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative clinical trial study of the therapeutic effects and side effects of the two drugs Baricitinib and Tofacitinib in pediatric patients with Alopecia Areata

Protocol summary

Study aim
Comparison of the effects of Baricitinib and Tofacitinib in pediatric patients with alopecia areata

Design
After obtaining written consent from the parents, the patients will be randomly divided into 2 groups of 24 people based on the randomization table. The first group will be treated with tofacitinib 5 to 15 mg per day, the second group will be treated with baricitinib 2 to 4 mg per day.

Settings and conduct
After obtaining written consent from the parents, the patients will be randomly divided into 2 groups of 24 people based on the randomization table and the order of entry into the study. The first group will be treated with Tofacitinib 5 to 15 mg per day, the second group will be treated with Baricitinib 2 to 4 mg per day. Clinical and laboratory evaluation intervals will be the first month, the third month, and the sixth month.

Participants/Inclusion and exclusion criteria
This study is a clinical trial and will be conducted on 48 pediatric patients with alopecia areata referred to Razi Hospital under the age of 18. Criteria for entering the study: 1) SALT score above 20% 2) consent of the child's parent and signing the consent form to enter the clinical trial 3) possibility of regular follow-up in the clinic Exclusion criteria: 1) Existence of underlying systemic diseases 2) Parents' lack of consent to systemic treatment 3) SALT score lower than 20

Intervention groups
This study is a clinical trial and will be conducted on 48 pediatric patients with alopecia areata referred to Razi Hospital under the age of 18. After obtaining written consent from the parents, the patients will be randomly divided into 2 groups of 24 people. The first group will be treated with tofacitinib 5 to 15 mg per day, the second group will be treated with baricitinib 2 to 4 mg per day.

Main outcome variables
Disease severity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240920063104N1**
Registration date: **2024-10-12, 1403/07/21**
Registration timing: **prospective**

Last update: **2024-10-12, 1403/07/21**
Update count: **0**

Registration date
2024-10-12, 1403/07/21

Registrant information

Name
Alireza Banani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8803 3928

Email address
alirezabanani1374@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-21, 1403/10/01

Expected recruitment end date
2025-06-22, 1404/04/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative clinical trial study of the therapeutic effects and side effects of the two drugs Baricitinib and Tofacitinib in pediatric patients with Alopecia Areata

Public title

A comparative clinical trial study of the therapeutic effects and side effects of the two drugs Baricitinib and Tofacitinib in pediatric patients with Alopecia Areata

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1) SALT score above 20% 2) Consent of the child's parent and signing of the consent form to enter the clinical trial 3) Possibility of regular follow-up in the clinic

Exclusion criteria:

Existence of underlying systemic diseases Parents' lack of satisfaction with systemic treatment SALT score lower than 20

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a clinical trial and will be conducted on 48 pediatric patients with alopecia areata referred to Razi Hospital under the age of 18. After obtaining written consent from the parents, the patients will be randomly divided into 2 groups of 24 people according to the randomization table. The first group will be treated with tofacitinib 5 to 15 mg per day, the second group will be treated with baricitinib 2 to 4 mg per day.

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

Ethics Committee of School of Medicine - Tehran University of Medical Sciences

Street address

No. 14, 46 Alley, Jamaluddin Asadabadi St., Yusuf Abad

City

Tehran

Province

Tehran

Postal code

1436773484

Approval date

2024-08-19, 1403/05/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.215

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

Comparison of the effects of Baricitinib and Tofacitinib in pediatric patients with alopecia areata

Timepoint

The beginning of the study, 1 month later, 3 months later and 6 months later

Method of measurement

According to clinical examination and SALT score

Secondary outcomes

1

Description

Comparison of the effects of baricitinib and tofacitinib in pediatric patients with alopecia areata

Timepoint

The beginning of the study, one month later, three months later and six months later

Method of measurement

Clinical examination and SALT score

Intervention groups

1

Description
Intervention group:children aged 2 to 18 years with alopecia areata receiving tofacitinib
Category
Treatment - Drugs

2

Description
Intervention group: children aged 2 to 18 years with alopecia areata receiving Baricitinib
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi dermatology hospital
Full name of responsible person
Dr Alireza Banani
Street address
No. 14, Alley 46, Jamaluddin Asadabadi St., Yusuf Abad
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1436773484
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alirezabanani1374@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ali Akbari Sari
Street address
No. 14, Alley 46, Jamaluddin Asadabadi St., Yusuf Abad
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Alireza Banani
Position
Dermatology resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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Other areas of specialty/work
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Total potential data after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Scientific and academic researchers related to the field of dermatology, provided the data source is mentioned
From where data/document is obtainable
alirezabanani1374@gmail.com
What processes are involved for a request to access data/document
Emailing identification documents and purposes of receiving data to the email address: alirezabanani1374@gmail.com Estimated time to send data: 1 week
Comments