Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Efficacy and Safety of Baricitinib versus Azathioprine in Combination with Topical Corticosteroids in Moderate-to-Severe Atopic Dermatitis Patients: Randomized Clinical Trial

Protocol summary

Study aim

This trial will be conducted to test the hypothesis that baricitinib 4-mg daily in combination with TCS is superior to azathioprine 1.5-2.5 mg/kg a day in combination with TCS for moderate-to-severe AD at week 12 in terms of efficacy and safety.

Design

Study BAAZ-AD-IR is a single-center, randomized, parallel-group, open-label, outpatient trial

Settings and conduct

In this study, patients with moderate to severe atopic dermatitis (eczema) who refer to the specialized clinic of Bo Ali Hospital located in Sari city of Mazandaran province and meet the inclusion criteria will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a minimum age of 18 years and maximum 75 years at the time of informed consent Patients with moderate to severe atopic dermatitis which is defined as having Eczema Area and Severity Index (EASI) ≥ 16, validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) ≥ 3, and body surface area (BSA) affected ≥10% Exclusion criteria: Patients who are currently suffering from or have a history of any concurrent skin disorders that would interfere with assessments of the study medication's effect on atopic dermatitis. Patients who have a known hypersensitivity to baricitinib or azathioprine or any component of these investigational products

Intervention groups

Intervention group: Group A includes patients who will receive baricitinib 4-mg daily plus fluocinolone 0.025% topical ointment and daily emollient of urea 10% topical cream for 12 weeks. Intervention group: Group B includes patients who will receive azathioprine 1.5-2.5 mg/kg plus fluocinolone 0.025% topical ointment and daily emollient of urea 10% topical cream for 12 weeks.

Main outcome variables

Eczema Area and Severity Index (EASI)

General information

Reason for update

Acronym

BAAZ-AD-IR

IRCT registration information

IRCT registration number: **IRCT20160427027636N6**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**
Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

Ghasem Rahmatpour Rokni

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-15, 1402/05/24

Expected recruitment end date

2024-08-14, 1403/05/24

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy and Safety of Baricitinib versus Azathioprine in Combination with Topical Corticosteroids in Moderate-to-Severe Atopic Dermatitis Patients: Randomized Clinical Trial

Public title
Baricitinib versus Azathioprine in Moderate-to-Severe Atopic Dermatitis Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a minimum age of 18 years and maximum 75 years at the time of informed consent Patients who can read, understand, and provide written informed consent Individuals with atopic dermatitis who have had a diagnosis for at least 12 months before to screening, as defined by the American Academy of Dermatology: Guidelines of care for the management of atopic dermatitis; Section 1. Diagnosis and assessment of atopic dermatitis Patients with moderate to severe atopic dermatitis which is defined as having Eczema Area and Severity Index (EASI) ≥ 16, validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) ≥ 3, and body surface area (BSA) affected ≥10% Individuals who have a documented history of insufficient response to topical treatments (at least a moderate potency topical corticosteroids and/or cyclosporine for at least 4 weeks or the maximum duration recommended for the product prescribed) within the 6 months before screening determined by a dermatologist
Exclusion criteria:
Patients who are currently suffering from or have a history of any concurrent skin disorders that would interfere with assessments of the study medication's effect on atopic dermatitis. For example, psoriasis or lupus erythematosus or eczema herpeticum, or erythrodermic, refractory, or unstable skin disease, including, but not limited, eczema that requires hospitalizations and/or intravenous treatment for skin infections Patients who have a known hypersensitivity to baricitinib or azathioprine or any component of these investigational products Patients with any major concomitant disease that is expected to need the administration of systemic corticosteroids, such as unstable chronic asthma, or who otherwise interfere with trial participation or require active regular monitoring. Patients who have been treated (1) Treatment with azathioprine in the previous 3 months (2) Having an experience of treatment with any oral JAK inhibitors including baricitinib < 4 weeks prior to randomization (3) Fusion proteins that target inflammatory pathways or monoclonal antibodies for less than 5 half-lives before randomization (4) Any parenteral corticosteroid administered by intramuscular/intravenous/intra-articular injection within 6 weeks before randomization or is anticipated to require a parenteral injection of corticosteroids during the study (5) probenecid at the time of randomization that cannot be discontinued for the duration of the study
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were allocated randomly in a 1:1 ratio to either Baricitinib Azathioprine by using blocks of four which were generated via randomization.com (Block balanced randomization) and then imputed into the sealed envelopes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Patients who meet the eligibility criteria will be randomized in a 1:1 allocation ratio to enroll in this study.Before randomization, patients will be screened based on inclusion and exclusion criteria and will discontinue tropical and systemic treatments for atopic dermatitis for 2-weeks (washout period) and will not be allowed to use them during the study. In visit 1 which will be scheduled after the washout period, demographic information and baseline assessment will be conducted and patients will randomize into arms, baricitinib 4-mg daily plus fluocinolone 0.025% topical ointment and daily emollient of urea 10% topical cream (Arm A), azathioprine 1.5-2.5 mg/kg plus fluocinolone 0.025% topical ointment and daily emollient of urea 10% topical cream (Arm B). Six weeks after visit 1, Visit 2 will be set to follow up on the patient condition, particularly in terms of adverse effects, and reorder their intervention. Visit 3 will be 12 weeks after visit 1 to perform the final assessment.Laboratory tests will be collected at baseline (as part of eligibility criteria) and final assessment.

Secondary Ids

1

Registry name
www.clinicaltrial.gov
Secondary trial Id
NCT05969730
Registration date
2023-07-23, 1402/05/01

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committee of Mazandaran University of Medical Sciences
Street address
15th Khordad avenue-Barab clinic- Sari -Iran
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Province
Mazandaran
Postal code
1234567898
Approval date
2023-07-12, 1402/04/21
Ethics committee reference number
IR.MAZUMS.REC.1402.214

Health conditions studied

1

Description of health condition studied
Moderate-to-Severe Atopic Dermatitis Patients
ICD-10 code
L20
ICD-10 code description
Atopic dermatitis

Primary outcomes

1

Description
Eczema Area and Severity Index (EASI)
Timepoint
12 weeks
Method of measurement
Through physician assessment using the EASI form

Secondary outcomes

1

Description
Validated Investigator’s Global Assessment for Atopic Dermatitis (vIGA-AD)
Timepoint
12 weeks
Method of measurement
Physician assessment using the vIGA-AD form

2

Description
SCORing Atopic Dermatitis (SCORAD)
Timepoint
12 weeks
Method of measurement
Physician assessment using the SCORAD form

3

Description
Dermatology Life Quality Index (DLQI)
Timepoint
12 weeks
Method of measurement
Patients Reported Outcome (PRO)

4

Description
Itch Numeric Rating Scale (Itch NRS)
Timepoint
12 weeks
Method of measurement
Patients Reported Outcome (PRO)

5

Description
Skin Pain Numeric Rating Scale (Skin Pain NRS)
Timepoint
12 weeks
Method of measurement
Patients Reported Outcome (PRO)

6

Description
Atopic Dermatitis Sleep Scale (ADSS)
Timepoint
12 weeks
Method of measurement
Patients Reported Outcome (PRO)

7

Description
Patient-Oriented Eczema Measure (POEM)
Timepoint
12 weeks
Method of measurement
Patients Reported Outcome (PRO)

8

Description
Hospital Anxiety Depression Scale (HADS)
Timepoint
12 weeks
Method of measurement
Patients Reported Outcome (PRO)

Intervention groups

1

Description
Intervention group: Group A includes patients who will

receive baricitinib 4-mg daily plus fluocinolone 0.025% topical ointment and daily emollient of urea 10% topical cream for 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Group B includes patients who will receive azathioprine 1.5-2.5 mg/kg plus fluocinolone 0.025% topical ointment and daily emollient of urea 10% topical cream for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Dermatology, Bou-Ali Sina Hospital

Full name of responsible person

Ghasem Rahmatpour Rokni

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

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

Mazandaran University of Medical Sciences

Proportion provided by this source

20

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

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Malekan

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Position
Medical Intern

Latest degree
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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
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The study report in the form of an article, the English protocol of the study and the raw data of the study will be available for publication after completion.

When the data will become available and for how long
Permanently

To whom data/document is available
All readers and researchers

Under which criteria data/document could be used
For transparency and reuse in systematic analyses

From where data/document is obtainable
Mohammad Malekan malekan.mohammad78@gmail.com

What processes are involved for a request to access data/document
By email with the approval of the group active in the study

Comments