

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 $\geq 10\%$ 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

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Iran (Islamic Republic of)

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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 $\geq 10\%$ 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 topical 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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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

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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

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