

Azathioprine combined with narrowband UVB 311 nm phototherapy for adults with atopic dermatitis

Submission date 02/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 06/10/2026	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 06/10/2026	Condition category Skin and Connective Tissue Diseases	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

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Study information

Scientific Title

Efficacy and safety of combined azathioprine and narrowband UVB 311 nm therapy for atopic dermatitis

Study objectives

To evaluate the efficacy and safety of azathioprine plus narrowband UVB 311 nm phototherapy compared with narrowband UVB 311 nm phototherapy alone in adults with moderate-to-severe atopic dermatitis.

Ethics approval required

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Ethics approval(s)

Approved 07/11/2024, Local Ethics Committee of Sechenov First Moscow State Medical University (Sechenov University) (1 Abrikosovsky Lane, building 1, moscow, 119435, Russian Federation; +7 (495) 622-97-06; lec_diss@staff.sechenov.ru), ref: 27-24

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Atopic dermatitis

Interventions

Participants were randomized 1:1 into two parallel groups. The combination group received azathioprine 100 mg/day for 4 weeks together with narrowband UVB 311 nm phototherapy three times weekly. The control group received narrowband UVB 311 nm phototherapy three times weekly. NB-UVB was administered using a Waldmann 7001 device. The initial dose was 50–70% of the minimal erythema dose and was adjusted according to skin phototype and erythema response. Topical treatment was individualized according to clinical guidelines. Prohibited therapies were discontinued before enrollment according to a predefined washout period.

Intervention Type

Drug/Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Azathioprine, narrowband UVB 311 nm phototherapy (Waldmann 7001)

Primary outcome(s)

1. Atopic dermatitis severity measured using the Scoring Atopic Dermatitis (SCORAD) index at baseline and 4 weeks

Key secondary outcome(s)

Completion date

09/07/2026

Eligibility

Key inclusion criteria

Adults aged 18–70 years

Moderate-to-severe atopic dermatitis refractory to previous therapy, diagnosed according to the Hanifin and Rajka criteria, and disease severity was assessed using the SCORAD index and Investigator's Global Assessment (IGA)

Provided written informed consent

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

70 Years

Sex

All

Total final enrolment

60

Key exclusion criteria

1. Autoimmune or malignant diseases
2. Pregnancy or lactation
3. Photodermatosis
4. Refusal or withdrawal of consent
5. Active infection
6. Severe chronic comorbidities
7. Use of concomitant treatments affecting study outcomes
8. Use of photosensitizing medications
9. Melanoma or non-melanoma skin cancer
10. Severe hepatic or renal impairment
11. Severe anemia, leukopenia, or thrombocytopenia
12. TPMT deficiency
13. Severe treatment-related adverse events, including hepatotoxicity, myelosuppression, and phototoxicity

Date of first enrolment

11/11/2024

Date of final enrolment

09/01/2026

Locations**Countries of recruitment**

Russian Federation

Sponsor information**Organisation**

Sechenov First Moscow State Medical University (Sechenov University)

Funder(s)**Funder type****Funder Name**

I.M. Sechenov First Moscow State Medical University

Alternative Name(s)

Moscow State Medical University, Sechenov University, MSMU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Russian Federation

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available