

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the effect of oral melatonin versus placebo in controlling pruritus in patients with atopic dermatitis: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of oral melatonin versus placebo in controlling pruritus in patients with atopic dermatitis

Design

This is a Phase III double-blind randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Sina Hospital in Hamadan city, involving 60 eligible patients with atopic dermatitis. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 12 to 65 years; Atopic dermatitis.
Exclusion criteria: Pregnancy or breastfeeding; Liver, kidney, nervous or immune system disease; Use of warfarin and fluvoxamine

Intervention groups

Intervention group: Routine treatment includes combined urea 10% and Eucerin 90% ointment and fluocinolone 30% and Eucerin 70% ointment daily plus oral 3 mg melatonin supplement daily for 6 weeks. Control group: Routine treatment includes combined urea 10% and Eucerin 90% ointment and fluocinolone 30% and Eucerin 70% ointment daily plus oral placebo supplement daily for 6 weeks.

Main outcome variables

The intensity of itching, severity of atopic dermatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N483**

Registration date: **2023-09-29, 1402/07/07**

Registration timing: **prospective**

Last update: **2023-09-29, 1402/07/07**

Update count: **0**

Registration date

2023-09-29, 1402/07/07

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-12, 1402/07/20

Expected recruitment end date

2025-03-10, 1403/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral melatonin versus placebo in controlling pruritus in patients with atopic dermatitis: a

double-blind randomized clinical trial

Public title

Effect of oral melatonin in controlling pruritus in patients with atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 12 to 65 years Atopic dermatitis

Exclusion criteria:

Pregnancy or breastfeeding Liver, kidney, nervous or immune system disease Use of warfarin and fluvoxamine

Age

From **12 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, 60 sheets of paper will be prepared - 30 with the name of the intervention and 30 with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. The process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

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Postal code

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Approval date

2023-07-22, 1402/04/31

Ethics committee reference number

IR.UMSHA.REC.1402.358

Health conditions studied

1

Description of health condition studied

Atopic dermatitis

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

Primary outcomes

1

Description

The intensity of itching

Timepoint

Before the intervention and then 2, 4 and 6 weeks after the intervention

Method of measurement

Using visual analog scale (VAS)

2

Description

Severity of atopic dermatitis

Timepoint

Before the intervention and then 2, 4 and 6 weeks after the intervention

Method of measurement

Using the Scoring Atopic Dermatitis tool (SCORAD)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment includes combined urea 10% and Eucerin 90% ointment and fluocinolone 30% and Eucerin 70% ointment daily plus oral 3 mg melatonin supplement daily for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: Routine treatment includes combined urea 10% and Eucerin 90% ointment and fluocinolone 30% and Eucerin 70% ointment daily plus oral placebo supplement daily for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Sina Hospital

Full name of responsible person

Dr. Ayda Nouri Danesh

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Sina Hospital, Mirzadeh Eshghi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Ayda Nouri Danesh

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available