

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effect of topical betamethasone with oral melatonin in the treatment of atopic dermatitis

Protocol summary

Study aim

Determining and comparing the effect of topical betamethasone with oral melatonin in the treatment of atopic dermatitis

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 50 patients

Settings and conduct

In this randomized double-blind clinical trial study, 50 patients referred to Alzahra and Sedigheh Tahereh hospitals in Isfahan will be included in the study and randomly divided into two groups. One group will receive the usual treatment with melatonin tablets and the other group will receive the usual treatment with placebo tablets. Then the scaling severity, blister severity, redness severity, and dermatitis severity of patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-65 years and consent to participate in the study. Non inclusion criteria: extent of involvement less than 2% or more than 30% of the body surface, skin problems other than atopic dermatitis, severe systemic diseases (kidney disease, diabetes, uncontrollable hypertension, and other chronic diseases), consumption of systemic medications for atopic dermatitis 4 weeks before the start of the study, use of topical medications for atopic dermatitis 2 weeks before the start of the study.

Intervention groups

Intervention group: In this group, patients receive topical betamethasone and an emollient twice a day. They are also prescribed an oral melatonin 3 mg tablet at bedtime. Control group: In this group, patients receive topical betamethasone and an emollient twice a day. They are also prescribed a placebo tablet (which looks similar to melatonin).

Main outcome variables

Scaling severity; Blister severity; Redness severity; Dermatitis severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N23**

Registration date: **2021-02-14, 1399/11/26**

Registration timing: **prospective**

Last update: **2021-02-14, 1399/11/26**

Update count: **0**

Registration date

2021-02-14, 1399/11/26

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-18, 1399/11/30

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of topical betamethasone with oral melatonin in the treatment of atopic dermatitis

Public title
The effect of topical betamethasone and oral melatonin in the treatment of atopic dermatitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-65 years Satisfaction to participate in the study
Exclusion criteria:
Extent of involvement less than 2% or more than 30% of the body surface Skin problems other than atopic dermatitis Severe systemic diseases (kidney disease, diabetes, uncontrolled hypertension, and other chronic diseases) Use of systemic medications for atopic dermatitis 4 weeks before the start of the study Use of topical medications for atopic dermatitis 2 weeks before the start of the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 50 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the two drugs melatonin and placebo of the same color and shape are prepared by the pharmacist and placed in coded packages and given to the doctor. He prescribes them without knowing the type of each drug. Also, the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2020-08-22, 1399/06/01

Ethics committee reference number

IR.MUI.MED.REC.1399.422

Health conditions studied

1

Description of health condition studied

Atopic dermatitis

ICD-10 code

L20.9

ICD-10 code description

Atopic dermatitis, unspecified

Primary outcomes

1

Description

Scaling severity

Timepoint

4, 8 and 12 weeks and 3 months after intervention

Method of measurement

Scoring Index for Atopic Dermatitis (SCORAD)

2

Description

Blister severity

Timepoint

4, 8 and 12 weeks and 3 months after intervention

Method of measurement

Scoring Index for Atopic Dermatitis (SCORAD)

3

Description

Redness severity

Timepoint

4, 8 and 12 weeks and 3 months after intervention

Method of measurement

Scoring Index for Atopic Dermatitis (SCORAD)

4

Description

Dermatitis severity

Timepoint

4, 8 and 12 weeks and 3 months after intervention

Method of measurement

Scoring Index for Atopic Dermatitis (SCORAD)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group, patients receive topical betamethasone and an emollient twice a day. They have also prescribed a placebo tablet (which looks similar to melatonin) at bedtime.

Category

Placebo

2

Description

Intervention group: In this group, patients receive topical betamethasone and an emollient twice a day. They have also prescribed an oral melatonin 3 mg tablet at bedtime.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Fariba Iraj

Street address

Skin department; Al-Zahra Hospital; Al-Zahra Educational and Medical Center; Soffah boulevard; Shahid Keshvari highway

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

iraji@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Sedigheh Tahereh Clinic

Full name of responsible person

Fariba Iraj

Street address

Dermatology Department, Sedigheh Tahereh Clinic, Khoram street

City

Isfahan

Province

Isfahan

Postal code

8139946111

Phone

+98 31 3335 9797

Email

iraji@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fariba Iraj

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Skin department; Al-Zahra Hospital; Al-Zahra Educational and Medical Center; Soffah boulevard; Shahid Keshvari highway

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

iraji@med.mui.ac.ir

8174675731

Phone

+98 31 3620 2020

Email

iraji@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Saeid Karami

Position

general physician

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Skin department; Al-Zahra Hospital; Al-Zahra Educational and Medical Center; Soffah boulevard; Shahid Keshvari highway

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

saeidkarami3372@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fariba Iraj

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Skin department; Al-Zahra Hospital; Al-Zahra Educational and Medical Center; Soffah boulevard; Shahid Keshvari highway

City

Isfahan

Province

Isfahan

Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not 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

No - There is not 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