Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The investigation of the effect of Melatonin Supplement on Dermatitis Severity in Patients: a randomized, double-blinded, placebo-controlled clinical trial

Protocol summary

Study aim

Determining the effect of melatonin supplementation on the severity of symptoms and pain intensity, itching, sleep quality and quality of life in dermatitis patients.

Design

Clinical trial with control group, parallel groups, double blind, randomized, phase 3 on 80 patients. Permuted Block is used for randomization.

Settings and conduct

After admitting the patient in Karaj Imam Ali Hospital by a clinician, the patient (if included) is randomly assigned to one of the study groups. Demographic information, underlying diseases, medications and patient habits will be recorded. The patient will be visited at the beginning and end of the study. Dermatitis severity will assessed with SCORAD index, patient s sleep quality with ISI and ADSS index, quality of life with DLQI, pain with NRS index and pruritus with 12-PSS index at the beginning and end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 12 years of age or older patients with dermatitis and at least 5% whole body involvement and informed written consent. Exclusion criteria: Patients who receive systemic treatment for their dermatitis (exception: antihistamines), use sedatives, have a history of allergic reactions to Melatonin or other ingredients in tablets. If a patient does not want to continue the study at any time after the study has started.

Intervention groups

Patients in drug group receive a tablet containing 10 mg of melatonin from Jalinous pharmaceutical company, at night, 1 hour before bed for 4 weeks. The placebo group receives an ineffective pill with similar appearance to melatonin tablet, for 4 weeks, at night 1 hour before bedtime. In both groups, patients receive routine and main dermatitis treatment regimen.

Main outcome variables

Improvement of severity of symptoms, pain intensity, itching, sleep quality and quality of life in dermatitis patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220331054378N1**
Registration date: **2022-04-23, 1401/02/03**
Registration timing: **prospective**

Last update: **2022-04-23, 1401/02/03**
Update count: **0**

Registration date

2022-04-23, 1401/02/03

Registrant information

Name

Ghazal Gharibi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3256 7175

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ghazal.gharibi98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-07, 1401/04/16

Expected recruitment end date

2022-10-08, 1401/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation of the effect of Melatonin Supplement on Dermatitis Severity in Patients: a randomized, double-blinded, placebo-controlled clinical trial

Public title

The investigation of the Effect of Melatonin Supplement on Dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

12 year-old or older patients with dermatitis which has affected at least 5% of whole body Signing the consent form by the patient.

Exclusion criteria:

Patients receiving systemic treatment for their dermatitis (exception: antihistamines). Patients receiving sedatives. Patients with history of allergic reactions to Melatonin or other ingredients in tablets. If a patient refuses to continue the study at any time after the study started.

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Being in melatonin tablet or placebo group is based on Permuted Block Randomization. Individual stratified randomization is performed. Random blocks are generated by computer statistical software. Patients enter blocks including four and receive melatonin tablet or placebo in a randomized manner. Allocation concealment is carried out. Physician, patient and first researcher are not aware of patients' group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The physician, the first researcher and patient are unaware of the melatonin or placebo allocation. The second researcher is not blinded. The second researcher repackages tablets of melatonin and placebo without name but with codes and gives them to the first researcher. The second researcher has no intervention in allocation of patients and outcome assessment. The first researcher receives packages containing melatonin or placebo and delivers them to patients. The first researcher is involved in outcome assessment and is unaware that patients receive melatonin or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Office of the Ethics Committee, Second floor, Deputy of Research and Technology, Saffarian Alley, 45 meter Golshahr, Karaj

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.ABZUMS.REC.1400.352

Health conditions studied

1

Description of health condition studied

Dermatitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of dermatitis

Timepoint

Beginning and the end of the study

Method of measurement

SCORAD index

Secondary outcomes

1

Description
Quality of Sleep
Timepoint
Beginning and the end of the study
Method of measurement
ISI and ADSS index

2

Description
Quality of Life
Timepoint
Beginning and the end of the study
Method of measurement
DLQI index

3

Description
Severity of pain
Timepoint
Beginning and the end of the study
Method of measurement
NRS index

4

Description
Severity of itching
Timepoint
Beginning and the end of the study
Method of measurement
12-PSS index

Intervention groups

1

Description
Intervention group: Patients in drug group receive a tablet containing 10 mg of melatonin from Jalinous pharmaceutical company, every night 1 hour before bed for 4 weeks. Patients also receive routine and main dermatitis treatment regimen.
Category
Treatment - Drugs

2

Description
Control group: The placebo group receives an ineffective pill for 4 weeks every night 1 hour before bedtime. Patients also receive routine and main dermatitis treatment regimen.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Hospital
Full name of responsible person
Maryam Daei
Street address
Imam Ali hospital, Valia'sr Ave, Shora Blvd, Azimieh, Karaj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Hatam Godini
Street address
Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr, Karaj
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Research@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz 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
Alborz University of Medical Sciences
Full name of responsible person
Maryam Daei
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data sharing is possible if asked
When the data will become available and for how long
After article acceptance
To whom data/document is available
Researchers working in scientific institutes and universities
Under which criteria data/document could be used
The data is only available for viewing.
From where data/document is obtainable
m.daei@abzums.ac.ir
What processes are involved for a request to access data/document
Up to one month after the announcement of the need
Comments