Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The investigation of the effect of melatonin topical cream on the lesions of patients with dermatitis

Protocol summary

Study aim

Determining the effect of melatonin topical cream on itching caused by dermatitis Determining the effect of melatonin topical cream on the severity of dermatitis lesions Determining the effect of melatonin topical cream on sleep quality in patients with dermatitis Determining the effect of melatonin topical cream on quality of life in patients with dermatitis Determining the effect of melatonin topical cream on pain in patients with dermatitis

Design

Clinical trial with control group, parallel groups, double blind, randomized, phase 3 on 60 patients. Permuted Block is used for randomization.

Settings and conduct

After admitting the patient by 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 be 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. If a patient does not want to continue the study at any time after the study has started.

Intervention groups

Patients in the drug group receive 6% melatonin topical cream twice daily for 3 weeks. The placebo group will receive a placebo cream for 3 weeks.

Main outcome variables

The severity of eczema, pruritus, pain, insomnia, the dermatitis sleep scale and the quality of life of patients are assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220403054394N1**
Registration date: **2022-06-04, 1401/03/14**
Registration timing: **prospective**

Last update: **2022-06-04, 1401/03/14**
Update count: **0**

Registration date

2022-06-04, 1401/03/14

Registrant information

Name

Zahra Davari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3256 7175

Email address

zadavari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-11, 1401/04/20

Expected recruitment end date

2022-10-12, 1401/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The investigation of the effect of melatonin topical cream on the lesions of patients with dermatitis

Public title
The effect of melatonin cream 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. Written informed consent to participate in study

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 creams. 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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Being in melatonin cream 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 or placebo cream in a randomized manner. Allocation concealment is carried out. Physician, patient and first researcher are not aware of patients' group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The physician, the first researcher and patient are unaware of the melatonin or placebo cream allocation. The second researcher is not blinded. The second researcher repackages cream 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 cream and delivers them to patients. The first researcher is involved in outcome assessment and is unaware that patients receive melatonin or placebo cream.

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 meters from Golshahr

City
karaj

Province
Alborz

Postal code
3198764653

Approval date
2022-03-08, 1400/12/17

Ethics committee reference number
IR.ABZUMS.REC.1401.001

Health conditions studied

1

Description of health condition studied
Dermatitis

ICD-10 code
L20-L30

ICD-10 code description
Diseases of the skin and subcutaneous tissue(L00-L99)

Primary outcomes

1

Description
Lesion severity in the dermatitis score questionnaire

Timepoint
At the beginning of the study and 21 days after starting the topical melatonin cream

Method of measurement
Severity Scoring of Atopic Dermatitis index (SCORAD) questionnaire

Secondary outcomes

1

Description
Severity of itching according to12-Item Pruritus Severity Scale(12-PSS)
Timepoint
At the beginning of the study and 21 days after starting the topical melatonin cream
Method of measurement
12-Item Pruritus Severity Scale(12-PSS)

2

Description
Pain intensity based on Numeric Rating Scale (NRS)
Timepoint
At the beginning of the study and 21 days after starting the topical melatonin cream
Method of measurement
Numeric Rating Scale (NRS)

3

Description
Insomnia severity based on insomnia severity index (ISI)
Timepoint
At the beginning of the study and 21 days after starting the topical melatonin cream
Method of measurement
insomnia severity index (ISI)

4

Description
Sleep Disorder on the Atopic Dermatitis Sleep Scale (ADSS)
Timepoint
At the beginning of the study and 21 days after starting the topical melatonin cream
Method of measurement
Atopic Dermatitis Sleep Scale (ADSS)

5

Description
Quality of life based on Dermatology Life Quality Index (DLQI)
Timepoint
At the beginning of the study and 21 days after starting the topical melatonin cream
Method of measurement
Dermatology Life Quality Index (DLQI)

Intervention groups

1

Description
Intervention group: Patients apply topical cream 6% melatonin twice a day for 3 weeks on their skin lesions. Patients receive routine and main dermatitis treatment regimen.
Category
Treatment - Drugs

2

Description
Control group: The placebo group receives a placebo twice a day for 3 weeks with a very similar appearance. Patients receive routine and main dermatitis treatment regimen.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali hospital
Full name of responsible person
Maryam Daei
Street address
Emam Ali hospital, Azimiyeh three ways, At the beginning of Chalous road
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m.daei@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Dr. Hatem Godini
Street address
Alborz University of Medical Sciences, Administrative Town, North Taleghani Boulevard, Taleghani Square
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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
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Maryam Daei
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Zahra Davari
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Student
Latest degree
A Level or less
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3154686689
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zadavari@gmail.com

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
Undecided - It is not yet known if there will be 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
The results of data is shareable
When the data will become available and for how long
It is not yet known

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

It is not yet known

From where data/document is obtainable

zadavari@gmail.com

What processes are involved for a request to access data/document

Formal request is required

Comments