

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Email address

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 Jalinus 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

##### **City**

Karaj

##### **Province**

Alborz

##### **Postal code**

3154686695

##### **Phone**

+98 26 3252 7576

##### **Email**

m.daei@abzums.ac.ir

## **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

##### **City**

Karaj

##### **Province**

Alborz

##### **Postal code**

3198764653

##### **Phone**

+98 26 3464 3705

##### **Email**

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

**Street address**

Next to the Imam Ali hospital, Valia'sr Ave, Shora Blvd, Azimieh, Karaj

**City**

Karaj

**Province**

Alborz

**Postal code**

3154686689

**Phone**

+98 26 3256 7175

**Email**

maryamdaei@yahoo.com

## Person responsible for scientific 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

**Street address**

Next to the Imam Ali hospital, Valia'sr Ave, Shora Blvd, Azimieh, Karaj

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3154686689

**Phone**

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**Email**

maryamdaei@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Alborz University of Medical Sciences

**Full name of responsible person**

Ghazal Gharibi

**Position**

Pharmacy student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Next to the Imam Ali hospital, Valia'sr Ave, Shora Blvd, Azimieh, Karaj

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**Province**

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**Postal code**

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**Phone**

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**Fax****Email**

ghazal.gharibi98@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**

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**