Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Survey the effect of melatonin supplementation on clinical symptoms and sleep quality in patients with rheumatoid arthritis

Protocol summary

Study aim
The aim of this study is to determine the effects of melatonin supplementation on clinical status and sleep quality in patients with rheumatoid arthritis.

Design
Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive melatonin supplement (n=35) or placebo (n=35).

Settings and conduct
Among patients with rheumatoid arthritis referred to rheumatology specialist office , 70 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. intervention: 8 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with rheumatoid arthritis.; aged 18 to 50 years; BMI 18/5 to 30; Exclusion criteria: Patients unwilling to continue the study, people taking antidepressants, sedatives such as sertraline and fluoxetine, people smoking and alcohol, use of antioxidant supplements in the last 3 months, people taking anticoagulants, pregnancy and Breastfeeding (women) and any disease other than rheumatoid arthritis

Intervention groups
Intervention group: 3 mg/day Melatonin (Norm life, Iran), one hour before bedtime for 8 weeks. Control group: Placebo, one hour before bedtime for 8 weeks.

Main outcome variables
sleep quality, pain intensity, and disease severity (primary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update
Due to the widespread prevalence of Covid19 disease in Ahvaz and the lack of cooperation of patients to receive blood samples and perform laboratory tests, as well as other problems that arose in this direction, it was decided to exclude laboratory tests from the study.

Acronym

IRCT registration information
IRCT registration number: **IRCT20191231045964N1**
Registration date: **2020-08-15, 1399/05/25**
Registration timing: **retrospective**

Last update: **2021-12-08, 1400/09/17**
Update count: **1**

Registration date
2020-08-15, 1399/05/25

Registrant information

Name
Tayebeh Palimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 5234 4108

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palimitayebeh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-04, 1399/02/15

Expected recruitment end date
2020-07-05, 1399/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Survey the effect of melatonin supplementation on clinical symptoms and sleep quality in patients with rheumatoid arthritis

Public title
Melatonin in rheumatoid arthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
They are eighteen to fifty years old Patients are selected from both sexes Patients with rheumatoid arthritis Patients' body mass index is between 18/5_30
Exclusion criteria:
People taking antidepressants and sedatives People who use alcohol and cigarettes Taking antioxidant supplements within 3 months prior People taking anticoagulants Pregnant and lactating women Any disease except rheumatoid arthritis
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes. Supplements and placebos are in the same packaging. Only the code is written on the packages. Patients and researchers do not know the type of intervention and after analyzing the data, packet codes are decoded.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz, Khosetan,Iran Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2020-01-11, 1398/10/21
Ethics committee reference number
IR.AJUMS.REC.1398.812

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis
ICD-10 code
M05
ICD-10 code description
Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description
Sleep quality
Timepoint
Before and after the intervention
Method of measurement
Questionnaire

2

Description
Intensity of pain
Timepoint
Before and after the intervention
Method of measurement
VAS Questionnaire

3

Description
Illness severity
Timepoint
Before and after the intervention
Method of measurement
DAS-28 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One 3 mg melatonin capsule, daily, for 2 months
Category
Treatment - Drugs

2

Description
Control group: One 3 mg placebo capsule, daily, for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology Specialist Office
Full name of responsible person
Dr. Majid Karandish
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz, Khosetan,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz 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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Tayebeh Palimi
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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