

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

Email address

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

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8253

Email

palimitayebeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badawi

Street address

Golestan Highway

City

Ahwaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3336 2414

Fax

+98 61 3336 2414

Email

badavi-m@ajums.ac.ir

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

Nutrition

Street address

Nutrition Department, Para-Medical School, Ahvaz
Jundishapur University of Medical Sciences,Golestan
highway

City

Ahwaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3373 8383

Email

palimitayebeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Majid Karandish

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition
Street address
Golestan Highway
City
Ahwaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8317
Email
mkarandish@yahoo.com

Person responsible for updating data

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
Nutrition
Street address
Nutrition Department, Para-Medical School, Ahvaz
Jundishapur University of Medical Sciences, Golestan
highway
City

Ahwaz
Province
Khouzestan
Postal code
6135715794
Phone
006133738383
Email
palimitayebeh@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

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