Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Sep 2026

The effects of melatonin supplementation on mean arterial pressure, pulse pressure, atherogenic index of plasma and new anthropometric index in type 2 diabetes mellitus patients

Protocol summary

Study aim

The purpose of this study is to investigate the effect of melatonin supplementation on mean arterial pressure, pulse pressure, atherogenic index of plasma and new anthropometric index in type 2 diabetes mellitus patients

Design

In this double-blind, single-center clinical trial 50 diabetic patients are selected and randomly divided into two intervention (n=25) and control (n=25) groups. Randomization will be done using a block design method

Settings and conduct

This study will be done in diabetes clinic of Golestan Hospital, Ahvaz. The researchers and patients will not inform about the allocation of subjects in the groups (double-blinded). Anthropometric and blood pressure indices will measure before and after the intervention.

Participants/Inclusion and exclusion criteria

inclusion criteria: diagnosed diabetes more than 5 years, aged 30-60 years. Exclusion criteria; Unwillingness to participate in the study, complications of diabetes mellitus such as kidney failure, insulin-dependent diabetic patients, pregnancy, lactation, travel for more than 2 weeks, smokers, use of food supplements, probiotics and anti-inflammatory drugs, as well as Using any antioxidant supplements in the last 3 months, using immunosuppressive medications, following specific diets, change of diet or deciding to lose weight in the last 6 months.

Intervention groups

The intervention group will receive two 3 mg Melatonin tablets (Nature Made, USA) per day, one hour before bedtime, for 60 days. The control group will receive two 3 mg placebo tablets (provided by Faculty of Pharmacy in Ahvaz Jundishapur University of Medical Sciences) containing cellulose, silicon dioxide,and starch one hour before bedtime, for 60 days.

Main outcome variables

Mean arterial pressure, pulse pressure, atherogenic index of plasma, a body shape index, abdominal volume index, body adiposity index, lipid accumulation product

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190303042905N1**
Registration date: **2019-05-17, 1398/02/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-17, 1398/02/27**
Update count: **0**

Registration date

2019-05-17, 1398/02/27

Registrant information

Name

Parichehr Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8670 5503

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amiriparichehr70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-03, 1397/12/12

Expected recruitment end date

2019-05-31, 1398/03/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of melatonin supplementation on mean arterial pressure, pulse pressure, atherogenic index of plasma and new anthropometric index in type 2 diabetes mellitus patients

Public title
The effects of melatonin supplementation on type 2 diabetes mellitus
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
age between 30-60 diagnosed diabetes more than 5 years
Exclusion criteria:
Unwillingness to participate in the study complications of diabetes mellitus such as kidney failure insulin-dependent diabetic patients pregnancy lactation travel for more than 2 weeks smokers use of food supplements probiotics and anti-inflammatory drugs Using any antioxidant supplements in the last 3 months using immunosuppressive medications following specific diets change of diet or deciding to lose weight in the last 6 months
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on inclusion criteria, 50 patients will be randomly allocated to placebo (n = 25) or intervention (n = 25) groups. Block design based on the combined analysis will be used for randomization. In fact, according to pattern and using two codes of A and B 6 groups with 4 blocks will be select. This work is repeated in 2 steps. At the end, two A and B codes will be assign to the 2 last people and the randomization will be complete (50 patients).
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients with type 2 diabetes who go to the diabetes Clinic of Department of Golestan Hospital are selected. Participants in this study and person who responsible for data collection are not aware of the type of drug used. Also, the researchers and patients are not aware of the contents of the packets (a double-blind). The coding in this study will be done by a person outside the study who has information about diabetes and knows what code is related to supplement and which is related to placebo. But do not have much information about the details of our research methods.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Ave, khuzestan, Ahvaz, Iran
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Khouzestan
Postal code
6135715794
Approval date
2019-03-02, 1397/12/11
Ethics committee reference number
IR.AJUMS.REC.1397.897

Health conditions studied

1

Description of health condition studied
type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
triglycerides
Timepoint
before and after intervention
Method of measurement
enzymatic assay by kit

Secondary outcomes

1

Description
high density lipoprotein
Timepoint
before and after intervention
Method of measurement
enzymatic assay by kit

2

Description
mean arterial pressure(MAP)
Timepoint
before and after intervention
Method of measurement
MAP(mmHg)=[systolic blood Pressure +(2×diastolic blood pressure)]/3

3

Description
pulse pressure(PP)
Timepoint
before and after intervention
Method of measurement
formula:PP(mmHg)= systolic blood pressure (mmHg) - diastolic blood pressure(mmHg)

4

Description
atherogenic index of plasma(AIP)
Timepoint
before and after intervention
Method of measurement
based on formula: AIP=log□triglycerides /high density lipoprotein□

5

Description
weight
Timepoint
before and after intervention
Method of measurement
with Seca scale, light clothes and precision of 0.1 kg

6

Description
waist circumference(WC)
Timepoint
before and after intervention
Method of measurement
a non-stretchable measuring tape as the smallest horizontal girth between the costal and iliac crests at minimal respiration

7

Description
A body shape index(ABSI)
Timepoint
before and after intervention
Method of measurement
based on formula: ABSI=waist circumfrence/(□Body mass index□^(2/3) □×height□^(1/2))

8

Description
Lipid Accumulation Product(LAP)
Timepoint
before and after intervention
Method of measurement
based on formula

9

Description
Abdominal volume index(AVI)
Timepoint
before and after intervention
Method of measurement
based on formula

10

Description
Body adiposity index(BAI)
Timepoint
before and after intervention
Method of measurement
based on formula

11

Description
Conicity
Timepoint
before and after intervention
Method of measurement
based on formula

Intervention groups

1

Description
Intervention group:intervention group receive two melatonin tablets(Nature Made, USA) (3 mg) per day for 60 days
Category
Other

2

Description
Control group: The control group receive 2 tablets of placebo 3 mg per day containing cellulose, silicone dioxide and starch (made by the Faculty of Pharmacy, Ahvaz Jundishapur University of Medical Sciences) for 60 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic of Golestan Hospital
Full name of responsible person
Alireza Rafati Navai
Street address
Diabetes clinic, Golestan Hospital, Golestan Ave, khuzestan, Ahvaz, Iran
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Web page address
https://hgolestan.ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
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Ahvaz Jundishapur University of Medical Sciences, Golestan Ave, khuzestan, Ahvaz, Iran
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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
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Parichehr Amiri
Position
Phd student
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to the financial support of this research by the Ahvaz Jundishapur University of Medical Sciences , data of the study will be published after the end of the intervention as an article.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable