

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 21 8670 5503

##### Email address

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##### 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

**City**

Ahvaz

**Province**

Khuzestan

**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 circumference/(Body mass index<sup>(2/3)</sup> ×height<sup>(1/2)</sup> )

## 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

**City**

Ahvaz

**Province**

Khuzestan

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**Email**

golestanhospital@ajums.ac.ir

**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

**Street address**

Ahvaz Jundishapur University of Medical Sciences,  
Golestan Ave, khuzestan, Ahvaz, Iran

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**Phone**

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info@ajums.ac.ir

**Web page address**

http://www.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**

Parichehr Amiri

**Position**

Phd student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ahmad Zare Javid

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Parichehr Amiri

**Position**

Ph.D student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

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4445561358

**Phone**

**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