

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Evaluation of the effects of Melatonin Supplementation on metabolic Syndrome components and plasma Leptin and Adiponectin levels in patients with metabolic Syndrome

#### Protocol summary

##### Summary

**Objectives:** The metabolic syndrome is a collection of metabolic risk factors that increases the risk of cardiovascular disease, type 2 diabetes and some cancers. Insulin resistance and accumulation of visceral fat are suggested as background. Melatonin is considered one of the strongest antioxidants in the body that improves insulin resistance and dyslipidemia. The main objective of this study is evaluation of the effects of Melatonin supplement on metabolic Syndrome components and plasma Leptin and Adiponectin levels in patients with metabolic Syndrome. **Design:** This study is a double blind randomized clinical trial. Blinding will be implemented on patients and researchers. 80 Patients with metabolic syndrome will be divided in two intervention (receiving Melatonin supplement) and placebo groups. **Setting and conduct:** The period of intervention is 12 weeks. Blood samples will be taken before and after of supplementation. **Participants (including major eligibility criteria):** Inclusion criteria will be age more than 18 years, waist circumference in men greater than or equal to 102 cm and in women greater than or equal to 88 cm and triglycerides levels greater than or equal to 150 mg/dL and exclusion criteria will be suffering from other liver diseases, cancer and autoimmune diseases. **Intervention:** One 5 mg Melatonin capsule per day in intervention group and one placebo capsule per day in placebo group for 12 weeks. **Main outcome measures:** metabolic Syndrome components and plasma Leptin and Adiponectin levels.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016111016123N11**  
Registration date: **2017-02-20, 1395/12/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-02-20, 1395/12/02

##### Registrant information

###### Name

Sima Jafarirad

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1373 8317

###### Email address

jafarirad-s@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2017-01-29, 1395/11/10

##### Expected recruitment end date

2017-09-21, 1396/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effects of Melatonin Supplementation on metabolic Syndrome components and plasma Leptin

and Adiponectin levels in patients with metabolic Syndrome

## Public title

Effects of Melatonin on Metabolic Syndrome disease

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Age 18 years and older; having at least two of the five metabolic syndrome criteria including waist circumference in men greater than or equal to 102 cm and in women greater than or equal to 88 cm; triglycerides levels (TG) greater than or equal to 150 mg/dL; low-density lipoprotein cholesterol levels (HDL-c) less than or equal to 40 mg/dL in men and less than or equal to 50 mg/dL in women; blood pressure greater than or equal to 130 mmHg or under treatment of Hypertension; fasting blood sugar greater than or equal to 100 mg/dL. b -exclusion criteria: history of alcohol consumption; chronic and acute liver disorders (hepatitis B, C, ...); biliary diseases; autoimmune diseases; cancer; cardiovascular diseases; pulmonary diseases; kidney diseases; pregnancy; breast-feeding; use of contraceptives; hepatotoxic drugs consumption; use of Mineral- multivitamin supplements; weight loss surgery in the recent year; weight loss program in 3 month ago; history of hypothyroidism; Cushing's syndrome.

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## 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, Ahvaz, Iran

## City

Ahvaz

## Postal code

## Approval date

2017-01-21, 1395/11/02

## Ethics committee reference number

IR.AJUMS.REC.1395.702

## Health conditions studied

### 1

#### Description of health condition studied

metabolic syndrome

#### ICD-10 code

E90

#### ICD-10 code description

Nutritional and metabolic disorders in diseases classified elsewhere

## Primary outcomes

### 1

#### Description

Triglyceride

#### Timepoint

before intervention and after 3 months

#### Method of measurement

serum level

### 2

#### Description

Total cholesterol

#### Timepoint

before intervention and after 3 months

#### Method of measurement

serum level

## Secondary outcomes

### 1

#### Description

High density lipoprotein (HDL)

#### Timepoint

before intervention and after 3 months

#### Method of measurement

serum level

### 2

#### Description

Low density lipoprotein (LDL)

#### Timepoint

before intervention and after 3 months

#### Method of measurement

serum level

### 3

**Description**

Leptin

**Timepoint**

before intervention and after 3 months

**Method of measurement**

serum level

### 4

**Description**

Adiponectin

**Timepoint**

before intervention and after 3 months

**Method of measurement**

serum level

### 5

**Description**

fasting blood sugar

**Timepoint**

before intervention and after 3 months

**Method of measurement**

serum level

### 6

**Description**

blood pressure

**Timepoint**

before intervention and after 3 months

**Method of measurement**

Blood Pressure Monitor

### 7

**Description**

waist circumference

**Timepoint**

before intervention and after 3 months

**Method of measurement**

Tape measure

### 8

**Description**

sleep quality

**Timepoint**

before intervention and after 3 months

**Method of measurement**

questionnaire

## Intervention groups

### 1

**Description**

Melatonin, Tab 5 mg, once a dayT 3 months

**Category**

Other

### 2

**Description**

Placebo, 5 mg, 3 months

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Emam Khomieni Hospital

**Full name of responsible person**

Mina Bahrami

**Street address**

Emam Khomieni Hospital, Azadegan, Ahvaz, Iran

**City**

Ahvaz

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technology, Ahvaz  
Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr.Makhmalzadeh

**Street address**

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

**City**

Ahvaz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research and Technology, Ahvaz  
Jundishapur University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Sima Jafarirad

**Position**

Ph.D

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*