

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

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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

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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

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

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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