Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effects of melatonin supplementation on lipid profile, glycemic index, oxidative stress and inflammatory biomarkers in obese patients with type 2 diabetes

Protocol summary

Study aim
The effects of melatonin supplementation on lipid profile, glycemic index, oxidative stress and inflammatory biomarkers in obese patients with type 2 diabetes

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 46 patients. Sealedenvelope.com is used for randomization.

Settings and conduct
Patients at Shariati Hospital in Tehran are randomly selected for a study. Both groups receive supplements and are monitored over a 12-week period. The main outcome variables are measured and compared at the start and end of the study.

Participants/Inclusion and exclusion criteria
Entry requirements: 1. At least 6 months and a maximum of 10 years have passed since the diagnosis of the disease by a doctor. 2. Having diabetes diagnosed based on laboratory findings and the opinion of an endocrinologist. 3. Being willing to cooperate in this study 4. Age above 30 and below 60 years 5. Body mass index above 30 and below 40 kg/m2 6. Patients who are not candidates for bariatric surgery Non-entry conditions: Pregnancy, breastfeeding, or plans to become pregnant within 6 months. History of infectious or inflammatory diseases, thyroid disorders, or thrombocytopenia. Receiving enteral or parenteral nutritional support. Taking omega-3 supplements or antioxidant vitamins. Use of glucocorticoid drugs, NSAIDs, thyroxine, or warfarin. Patients who change their drug dosage or type during the study.

Intervention groups
In this study, the intervention group receives two 5 mg melatonin supplements daily, while the control group receives two placebo capsules that mimic melatonin in appearance, color, smell, and taste, for a period of 10 weeks.

Main outcome variables
Oxidative stress and Inflammatory markers, Blood sugar, lipid, anthropometry, systolic and diastolic blood pressure, sleep quality score and ASCVD and Framingham criteria.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170202032367N11**
Registration date: **2025-03-16, 1403/12/26**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-16, 1403/12/26**
Update count: **0**

Registration date
2025-03-16, 1403/12/26

Registrant information

Name
Hossien Imani

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-21, 1403/09/01

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of melatonin supplementation on lipid profile, glycemic index, oxidative stress and inflammatory biomarkers in obese patients with type 2 diabetes

Public title

The effects of melatonin supplementation on lipid profile, glycemic index, oxidative stress and inflammatory biomarkers in obese patients with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

At least 6 months and a maximum of 10 years have passed since the diagnosis of the disease by a doctor. Having diabetes diagnosed based on laboratory findings and the opinion of an endocrinologist. Willingness to cooperate in this study Age above 30 and less than 60 years Body mass index above 30 and below 40 kg/m2 Patients who are not candidates for bariatric surgery

Exclusion criteria:

At least 6 months and at most 10 years have passed since the diagnosis of the disease by a doctor. Having diabetes diagnosed based on laboratory findings and the opinion of an endocrinologist. Being willing to cooperate in this study Being willing to cooperate in this study Body mass index above 30 and below 40 kg/m2 Patients who are not candidates for bariatric surgery

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

46 patients are randomly assigned to each group (A/B) using block randomization stratified by age (category 1: under 30/category 2: over 30) and gender (male/female). Random sequences were generated by generating a block random list from www.sealedenvelope.com in 12 blocks of size 4. Treatment allocation of participants, study personnel and outcome wishes were masked and concealed in sealed, opaque numbered envelopes with sequential publication. Patients were randomly divided into two groups in a ratio of 1:1.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Due to the fact that the placebo capsule is similar to melatonin in terms of appearance, color, smell, taste, and shape, the people participating in the experiment will not be able to differentiate between the melatonin capsule and the placebo. Blinding of the researcher will be done through the codes included in the packaging of the supplements.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Faculty of Nutrition Sciences and Dietetics, Hojat Dost Alley, Khanaderi, Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2024-09-23, 1403/07/02

Ethics committee reference number

IR.TUMS.SHARIATI.REC.1403.069

Health conditions studied

1

Description of health condition studied

Non-insulin-dependent type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Serum levels of lipid parameters (T.G, T.C, LDL, HDL)

Timepoint

Before the intervention and 12 weeks later

Method of measurement

Pars test kit and spectrophotometry method

2

Description
Serum levels of blood sugar profiles (FBS, HbA1C, HOMA-IR, HOMA-B)
Timepoint
Before the intervention and 12 weeks later
Method of measurement
Diagnostic kits

3

Description
Serum levels of oxidative stress markers (MDA)
Timepoint
Before the intervention and 12 weeks later
Method of measurement
Pars test kit and spectrophotometry method

4

Description
Serum levels of inflammatory markers (hs-CRP, IL-6, TNF-α)
Timepoint
Before the intervention and 12 weeks later
Method of measurement
kit Eliza

Secondary outcomes

1

Description
Systolic and diastolic blood pressure
Timepoint
Before the intervention and 12 weeks later
Method of measurement
Sphygmomanometer and calibrated stethoscope

2

Description
Sleep quality score
Timepoint
Before the intervention and 12 weeks later
Method of measurement
Sleep quality questionnaire

3

Description
Carbohydrate, protein, fat and fiber intake
Timepoint
Before the intervention and 12 weeks later
Method of measurement
24-hour food recall questionnaire

4

Description
New anthropometric indices (Tyg, WT, VAI, WT)
Timepoint
Before the intervention and 12 weeks later
Method of measurement
Calculate

5

Description
Calculating the risk of chronic diseases using the ASCVD and Framingham criteria
Timepoint
Before the intervention and 12 weeks later
Method of measurement
Calculate

Intervention groups

1

Description
Intervention group: Intervention group: Before starting the main intervention, all the selected people enter the Run-in period for two weeks, to collect complete information about the patients' food intake. Then, using a general questionnaire, information about age, gender, socio-economic status, education level, history of diseases and hospitalization, surgery and history of taking medicines, supplements and duration of disease will be taken from all people. At the beginning of the study and at the end of the 6th and 12th weeks of the study, in order to investigate the intervening factors of the diet, 24-hour food memory, which includes two non-holiday days and one holiday day, will be taken from the patients through interviews. At the end of the run-in period, people in the intervention group will receive 10 mg melatonin supplement (Karen company) in the form of two 5 mg supplements per day.
Category
Rehabilitation

2

Description
Control group: Control group: Before starting the main intervention, all the selected people enter the Run-in period for two weeks, to collect complete information about the patients' food intake. Then, using a general questionnaire, information about age, gender, socio-economic status, education level, history of diseases and hospitalization, surgery and history of taking medicines, supplements and duration of disease will be taken from all people. At the beginning of the study and at the end of the fifth and tenth weeks of the study, in order to investigate the intervening factors of the diet, 24-hour food memory, which includes two non-holiday days and one holiday day, will be taken from the patients through interviews. At the end of the run-in period, people in the control group will receive 2 placebo capsules, which are similar to melatonin in terms of appearance, color, smell, taste and shape, for 10 weeks.
Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Shariati Hospital
Full name of responsible person
Seyyed mohammad Alavi
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Shariati Hospital, Jalal Al Ahmad Street, North Kargar Street, Tehran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Hossein Imani
Position
Associate professor
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Other areas of specialty/work
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Person responsible for updating data

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Nutrition

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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