

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Clinical trial of the effect of melatonin supplementation compared with the placebo on metabolic profiles in patients with coronary heart disease and type 2 diabetes mellitus

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of melatonin supplementation on metabolic profiles in type 2 diabetes patients with coronary heart disease (CHD).

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive melatonin supplements (n=30) or placebo (n=30).

Settings and conduct

Among diabetic patients with CHD referred to Naghavi Cardiology Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 50-85 years diagnosed with type 2 diabetes patients with coronary heart disease will be included in this study. Exclusion criteria: Exclusion criteria: Consuming melatonin supplements within the last 3 months, having an acute myocardial infarction and cardiac surgery within the past 3 months, and the night shift workers.

Intervention groups

Intervention group: two melatonin capsules (NUTRALab, Canada, 10 mg, 5 mg each capsule, daily, for 12 weeks orally. Control group: two Placebo capsules (Barij Essence, Kashan, Iran), daily, for 12 weeks orally.

Main outcome variables

Markers of oxidative stress (primary outcomes) and lipid profiles, biomarkers of inflammation and insulin metabolism (secondary outcome)

General information

Reason for update

The updating process was done after publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051333941N1**

Registration date: **2017-06-06, 1396/03/16**

Registration timing: **retrospective**

Last update: **2019-11-10, 1398/08/19**

Update count: **2**

Registration date

2017-06-06, 1396/03/16

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-05-18, 1396/02/28

Expected recruitment end date

2017-05-31, 1396/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of melatonin supplementation compared with the placebo on metabolic profiles in patients with coronary heart disease and type 2 diabetes mellitus

Public title

Effect of supplementation in treatment of Coronary Heart Disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion Criteria: Subjects aged 50-85 years; diagnosed with type 2 diabetes, CHD and overweight.

Exclusion criteria:

Exclusion criteria: Consuming melatonin supplements within the last 3 months Having an acute myocardial infarction and cardiac surgery within the past 3 months The night shift workers

Age

From **50 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI and age. Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2017-05-17, 1396/02/27

Ethics committee reference number

IR.Kaums.REC.1396.26

Health conditions studied**1****Description of health condition studied**

Coronary Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischaemic heart disease, unspecified

Primary outcomes**1****Description**

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

2**Description**

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3**Description**

Total antioxidant capacity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Protein carbonyl

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

HDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

ELISA kit

5

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

7

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

ELISA kit

8

Description

Beck Depression Inventory

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

9

Description

Systolic blood pressure

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Manometer

10

Description

Diastolic blood pressure

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Manometer

11

Description

Beck Anxiety Inventory

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Melatonin supplements (NUTRALab, Scarborough, Canada), 5 mg, two capsules one hour before bedtime for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (Barij Essence, Kashan, Iran), two capsules one hour before bedtime for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Cardiology Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaei Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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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