Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 31 5546 3378

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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
Isfehan
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 Rajaee Avenue, Kashan
City
Kashan
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Isfehan
Postal code
8715988141
Phone
+98 31 5546 3378
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asemi_z@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard, Kashan
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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