

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of the effect of melatonin supplementation compared with the placebo on metabolic status and gene expression related to inflammation, insulin and lipid in diabetic hemodialysis patients

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of melatonin supplementation on metabolic profiles and gene expression related to inflammation, insulin and lipid in diabetic hemodialysis patients.

Design

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

Settings and conduct

Among diabetic hemodialysis patients referred to Akhavan Clinic, 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. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and end of the intervention. intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diabetic hemodialysis patients; aged 18 to 80 years. Exclusion criteria: Patients with infectious, inflammatory and malignant diseases, those taking melatonin supplements, antioxidant and/or anti-inflammatory supplements within 3 months prior to enrollment in the study, the night shift workers, subjects taking immunosuppressive and antibiotics medications, unwillingness to cooperate

Intervention groups

Intervention group: Melatonin supplements (Zahravi, Tabriz, Iran), 10 mg, two capsules (5 mg each) one hour before bedtime for 12 weeks orally. Control group: placebo (Zahravi, Tabriz, Iran), two capsules one hour before bedtime for 12 weeks orally.

Main outcome variables

Outcomes: markers of insulin metabolism (primary outcomes) and inflammatory factors, oxidative stress

biomarkers and gene expression related to insulin, lipid and inflammation, and parameters of mental health (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N31**

Registration date: **2018-02-14, 1396/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-17, 1398/07/25**

Update count: **1**

Registration date

2018-02-14, 1396/11/25

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-09, 1396/11/20

Expected recruitment end date

2018-02-24, 1396/12/05

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 status and gene expression related to inflammation, insulin and lipid in diabetic hemodialysis patients

Public title
Effect of melatonin supplementation in treatment of diabetic hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Inclusion criteria: diabetic hemodialysis patients
 Individuals aged 18 to 80 years old
Exclusion criteria:
 Exclusion criteria: Patients with infectious, inflammatory and malignant diseases those taking melatonin supplements, antioxidant and/or anti-inflammatory supplements within 3 months prior to enrollment in the study the night shift workers subjects taking immunosuppressive and antibiotics medications
 unwillingness to cooperate

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
At the onset of the study, after balanced blocked randomization, all participants will be allocated into two groups to take either melatonin or placebo.

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

8115187159

Approval date

2018-02-07, 1396/11/18

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.107

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

Insulin

Timepoint

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

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

3

Description

Insulin sensitivity

Timepoint

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

Method of measurement

Secondary outcomes

1

Description

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

2

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

3

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

4

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

7

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

8

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

9

Description

Expressed levels of TNF- α gene

Timepoint

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

Method of measurement

PCR

10

Description

Expressed levels of TGF- β gene

Timepoint

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

Method of measurement

PCR

11

Description

Expressed levels of IL-8 gene

Timepoint

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

Method of measurement

PCR

12

Description

Expressed levels of PPAR- γ gene

Timepoint

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

Method of measurement

PCR

13

Description

Expressed levels of LDLR gene

Timepoint

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

Method of measurement

PCR

14**Description**

Beck Depression Inventory

Timepoint

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

Method of measurement

Questionnaire

15**Description**

Beck Anxiety Inventory

Timepoint

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

Method of measurement

Questionnaire

16**Description**

Pittsburgh Sleep Quality Index

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 (Zahravi, Tabriz, Iran), 10 mg, two capsules (5 mg each) one hour before bedtime for 12 weeks orally.

Category

Treatment - Drugs

2**Description**

Control group: Placebo (Zahravi, Tabriz, Iran), two capsules one hour before bedtime for 12 weeks orally.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akhavan Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaee Avenue, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 4446 0180

Email

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

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Email

asemi_z@kaums.ac.ir

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

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

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Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address**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