

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

The effects of melatonin supplementation on oxidative stress, inflammatory biomarkers and lipid profile in diabetic patients with chronic kidney disease- a randomized trial

Protocol summary

Study aim

Determining the effects of melatonin supplementation on oxidative stress, inflammation and lipid parameters in diabetic patients with chronic kidney disease

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 48 patients. Sealed envelope.com is used for randomization.

Settings and conduct

Patients are randomly selected from Shariati hospital clinic patients, Tehran. The supplements are delivered to the patients of both groups and monitored during 10 weeks. At the beginning and end of the study, the main outcome variables are measured.

Participants/Inclusion and exclusion criteria

inclusion criteria: Age 25-65 years; Having CKD before dialysis stages (stage 3 to 4) which is diagnosed based on lab findings and the nephrologist diagnosis; Body mass index 20-30 kg/m²; Willingness to cooperate in study; not inclusion criteria: CKD due to autoimmune diseases and glomerulonephritis; Blood pressure > 160/100 mm Hg; Pregnancy or intention to become pregnant within the next 6 months, breastfeeding; Infectious, inflammatory diseases, thyroid gland disorders, thrombocytopenia; Being under EN and PN support; Taking omega-3 and antioxidant supplements (vitamin E, C, B6, selenium, zinc and beta-carotene separately) from 3 months before the study; Taking glucocorticoids with a dose of more than 5 mg, antibiotics, fluoxamin, NSAIDs, warfarin; smoking; night shift workers

Intervention groups

People in the intervention group will receive 2, 5 mg melatonin supplements daily, and in the control group will receive 2 placebo capsules that are similar to melatonin in terms of appearance, color, smell, taste, and shape, for 10 weeks.

Main outcome variables

Oxidative stress markers; Inflammatory markers; Lipid profile; Renal indicators; Systolic and diastolic blood pressure; FBS and serum insulin; Serum phosphorus levels; Sleep quality score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170202032367N9**

Registration date: **2023-08-11, 1402/05/20**

Registration timing: **prospective**

Last update: **2023-08-11, 1402/05/20**

Update count: **0**

Registration date

2023-08-11, 1402/05/20

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

2023-09-23, 1402/07/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of melatonin supplementation on oxidative stress, inflammatory biomarkers and lipid profile in diabetic patients with chronic kidney disease- a randomized trial

Public title
The effects of melatonin supplementation on oxidative stress, inflammatory biomarkers and lipid profile in diabetic patients with chronic kidney disease- a randomized trial

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age above 25 and below 65 years Having CKD in the stage before dialysis (stage 3 to 4) which is diagnosed based on laboratory findings and the opinion of a nephrologist. Body mass index above 20 and below 30 kg/m2 Willingness to cooperate in this study
Exclusion criteria:
Having CKD due to autoimmune diseases and glomerulonephritis Blood pressure higher than 100/160 mmHg Pregnancy or intention to become pregnant within the next 6 months, breastfeeding Infectious, inflammatory diseases, thyroid gland disorders, thrombocytopenia Being under enteral and parenteral nutritional support Taking omega-3 supplements and antioxidant supplements (vitamin E, vitamin C, vitamin B6, selenium, zinc and beta-carotene separately) from 3 months before entering the study Taking glucocorticoid drugs with a dose of more than 5 mg, antibiotics, fluoxamin, non-steroidal anti-inflammatory drugs, warfarin smoking People who have night shift jobs

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
48 Patients were randomly assigned to each group (A/B) using block randomization stratified based on age (category1:under 30/category2:above 30) and gender (male/female). Random sequences were generated by creating a blocked randomization list from

www.sealedenvelope.com in 12 blocks with a size of 4. Treatment allocation was masked from participants, study personnel, and outcome assessors and was concealed in sequentially numbered, sealed, opaque envelopes. Patients were randomly assigned into two groups in a 1:1 ratio.

Blinding (investigator's opinion)
Double 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
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Postal code
1417653761

Approval date
2023-07-23, 1402/05/01

Ethics committee reference number
IR.TUMS.SHARIATI.REC.1402.072

Health conditions studied

1

Description of health condition studied
Kidney disease in the stage before dialysis (stage 3 and 4)

ICD-10 code
N18.9

ICD-10 code description
Chronic kidney disease, unspecified

Primary outcomes

1

Description

Serum levels of oxidative stress markers (TAC, TOS , MDA)

Timepoint

Before the intervention and 10 weeks later

Method of measurement

Pars azmoon kit and spectrophotometry method

2

Description

Serum levels of inflammatory markers (hs-CRP, IL-6)

Timepoint

Before the intervention and 10 weeks later

Method of measurement

ELISA kit

Secondary outcomes

1

Description

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

Timepoint

Before the intervention and 10 weeks later

Method of measurement

Pars azmoon kit and spectrophotometry method

2

Description

Serum levels of renal indicators (Cr, BUN, uric acid)

Timepoint

Before the intervention and 10 weeks later

Method of measurement

Calorimetric detection kits

3

Description

Systolic and diastolic blood pressure

Timepoint

Before the intervention and 10 weeks later

Method of measurement

Sphygmomanometer and calibrated stethoscope

4

Description

Serum levels of fasting blood sugar and serum insulin

Timepoint

Before the intervention and 10 weeks later

Method of measurement

Diagnostic kits

5

Description

Serum phosphorus level

Timepoint

Before the intervention and 10 weeks later

Method of measurement

Calorimetric detection kit

6

Description

Sleep quality score

Timepoint

Before the intervention and 10 weeks later

Method of measurement

Sleep quality questionnaire (PSQI)

7

Description

Carbohydrate, protein, fat and fiber intake

Timepoint

Before the intervention and 5 and 10 weeks later

Method of measurement

24-hour dietary recall (24HR)

Intervention groups

1

Description

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, by using a general questionnaire, information about age, gender, socioeconomic status, education level, history of diseases and hospitalization, surgery and history of taking medicines, supplements, and the duration of the 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 recall, 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 2, 5 mg supplements per day.

Category

Rehabilitation

2

Description

Control 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, by using a general questionnaire, information about age, gender, socioeconomic status, education level, history of diseases and hospitalization, surgery and history of taking medicines, supplements, and the duration of the 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 recall, 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**

Shariati Hospital

Full name of responsible person

Sara Sadeghi

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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

Hossien Imani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Sara Sadeghi

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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