Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 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. Sealedenvelope.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)
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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

Tehran

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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 and10 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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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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