Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the effect of melatonin supplementation on Insulin metabolism markers, parameters of oxidative stress and gene expression of PPAR-γ & ox-LDL in patients with diabetic nephropathy

Protocol summary

Study aim

Evaluation of the effect of melatonin supplementation on Insulin metabolism markers, parameters of oxidative stress and gene expression of PPAR-γ & ox-LDL in patients with diabetic nephropathy

Design

In this research, 60 patients with diabetic nephropathy who are eligible will be selected. Participants are randomly divided into two groups of intervention and control by computer software. The design of the study is the parallel blind randomized clinical trial.

Settings and conduct

60 patients with diabetic nephropathy who are eligible and referred to kidney clinic of Beheshti hospital affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected. Fasting blood samples will be taken at baseline and after 12 weeks of intervention.

Participants/Inclusion and exclusion criteria

Diabetic nephropathy patients with GFR between 15 and 89 ml / min, moderate blood pressure, lack of willingness to cooperate, non-use of fluvoxamine and any antioxidant supplement, non-cardiovascular disease, cancer, inflammatory diseases, autoimmune and hyper, or Hypothyroidism, Lack of lactation and pregnancy, lack of working in the night shift, the absence of a specific disease that leads to hospitalization, lack of smoking and alcohol consumption, absence of urinary tract infection and any other proteinuria causes.

Intervention groups

Patients will be assigned to receive either melatonin (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Insulin resistance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150606022562N5**
Registration date: **2018-12-08, 1397/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-08, 1397/09/17**
Update count: **0**

Registration date

2018-12-08, 1397/09/17

Registrant information

Name
Fereshteh Bahmani
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 31 5554 0021
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of melatonin supplementation on Insulin metabolism markers, parameters of oxidative stress and gene expression of PPAR-γ & ox-LDL in patients with diabetic nephropathy

Public title
The effect of melatonin in patients with diabetic nephropathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
GFR 15 to 89 ml per minute Moderate blood pressure (systolic pressure 140-160 and diastolic pressure 80-100 mmHg) No specific cardiovascular disease, cancer, inflammatory diseases, autoimmune and hyper or hypothyroidism Non-presence of urinary tract infection and other factors of proteinuria

Exclusion criteria:
Special illness that leads to hospitalization. High blood pressure (systolic pressure upper than 160 and diastolic pressure upper than 100 mmHg) Unwillingness to cooperate Taking fluvoxamine and any antioxidant supplement Working at night shifts Smoking and alcohol consumption Breastfeeding and pregnancy

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed with simple method and random numbers generated by computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants, researchers, data collectors, evaluators and data analyzers are not aware of which group is placebo or supplemented melatonin 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 and health services

Street address
Kashan University of Medical Sciences, Ravand road

City
Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2018-11-05, 1397/08/14

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1397.64

Health conditions studied

1

Description of health condition studied
diabetic nephropathy

ICD-10 code
N08.3*

ICD-10 code description
Glomerular disorders in diabetes mellitus (E10-E14 with common fourth character .2†)

Primary outcomes

1

Description
Insulin

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

Method of measurement
Elisa kit

2

Description
Insulin resistance

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

Method of measurement
HOMA formula

Secondary outcomes

1

Description
Triglyceride
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Enzymatic kit

2

Description
HDL cholesterol
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Enzymatic kit

3

Description
Total cholesterol
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Enzymatic kit

4

Description
QUICKI
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Calculation using QUICKI formula

5

Description
plasma Malondialdehyde
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
by Spectrophotometry method

6

Description
plsma protein carbonyl
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
by Spectrophotometry method

7

Description
plasma total Gluthatione
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
by Spectrophotometry method

8

Description
plasma total antioxidant capacity
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
by Spectrophotometry method

9

Description
gene expression of PPAR-γ
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Real-Time PCR method

10

Description
gene expression of ox-LDL
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Real-Time PCR method

11

Description
C reactive protein
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
by turbidimetric method

12

Description
Nitric oxide
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
by Spectrophotometry method

Intervention groups

1

Description
Intervention group: Taking 10 mg melatonin at night for 12 weeks

Category
Treatment - Drugs

2

Description
Control group: Taking placebo for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti hospital
Full name of responsible person
Dr. Alireza Soleymani
Street address
Qotb –e Ravandi Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamid Reza Banafshe
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banafsheh_h@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
Dr. Fereshte Bahmani
Position
Associate Professor/ Academic staff member of the Department of Clinical Biochemistry
Latest degree
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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