

# 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- $\gamma$ & 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- $\gamma$  & 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)

##### Phone

+98 31 5554 0021

##### Email address

fbahmani@kaums.ac.ir

##### 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- $\gamma$  & 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

Isfahan

##### 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**

plasma 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.

**City**

Kashan

**Province**

Isfahan

**Postal code**

87159/81151

**Phone**

+98 31 5554 0026

**Fax****Email**

beheshthospital@kaums.ac.ir

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Hamid Reza Banafshe

**Street address**

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**Email**

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**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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Medical Faculty, Kashan University of Medical Sciences, Ravand road

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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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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Fereshteh Bahmani

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Associate Professor/ Academic staff member of the  
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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