# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Evaluation of the effect of melatonin supplementation on Carotid Intima-Media Thickness, pulse-wave velocity and serum levels of hs-CRP in patients with diabetic nephropathy

## Protocol summary

**Study aim**

Determining the effect of melatonin supplementation on Carotid intima-media thickness, pulse-wave velocity and serum levels of hs-CRP in patients with diabetic nephropathy

**Design**

Two arms; parallel groups; randomized trial with control; double-blind, phase 3, including 60 patients. randomization is achieved by using computer software.

**Settings and conduct**

This study will be done on 60 diabetic patients with proteinuria (based on inclusion criteria) in Kashan city. Patients will be recruited in Nephrology center of Shahid Beheshti hospital (associated with Kashan University of Medical Sciences) based on inclusion criteria. hs-CRP, CIMT and PWV will be measured before and after receiving the medication or placebo. radiologists and lab workers are kept blind.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Approved diabetes; Proteinuria > 500 mg per day; GFR between 15-89 mLit/min; HbA1c < 7.2; Systolic blood pressure between 140-160 mmHg and Diastolic blood pressure between 90-100 mmHg.
Exclusion Criteria: Systolic blood pressure > 160 mmHg or Diastolic blood pressure > 100 mmHg; Pregnant or Lactating; Smoker or alcohol abuser; Underlying diseases including cardiovascular diseases, cancer, autoimmune disorders and hypo or hyperthyroidism; Using fluvoxamine or antioxidant drugs; Urinary tract infection or other diseases that cause proteinuria; Night worker.

**Intervention groups**

Melatonin group which receives melatonin . control group which receives placebo .

**Main outcome variables**

Pulse wave velocity and Carotid intima-media thickness

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200527047584N2**
Registration date: **2020-07-21, 1399/04/31**
Registration timing: **retrospective**

Last update: **2020-07-21, 1399/04/31**
Update count: **0**

**Registration date**

2020-07-21, 1399/04/31

**Registrant information**

**Name**

Hamidreza Talari

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 5554 0026

**Email address**

talari_hr@kaums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-04-20, 1399/02/01

**Expected recruitment end date**

2020-06-21, 1399/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Evaluation of the effect of melatonin supplementation on Carotid Intima-Media Thickness, pulse-wave velocity and serum levels of hs-CRP in patients with diabetic nephropathy

**Public title**
Evaluation of the effect of melatonin supplementation on vascular diseases in patients with diabetic nephropathy
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Approved diabetes Proteinuria > 500 miligram per day GFR between 15-89 mLit/min HbA1c < 7.2 Systolic blood pressure between 140-160 mmHg and Diastolic blood pressure between 90-100 mmHg
**Exclusion criteria:**
Pregnant or Lactating Smoker or alcohol abuser Underlying diseases including cardiovascular diseases, cancer, autoimmune disorders and hypo or hyperthyroidism Using fluvoxamine or antioxidant drugs Urinary tract infection or other diseases that cause proteinuria Night worker
**Age**
From **40 years** old to **85 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
After specifying the sample size, blocks of size 4 consisting of A and B letters are formed (6 blocks). Then, each of the blocks is numbered 1 to 6 and based on the selected numbers from random numbers table, we form a sequence of blocks, in which the letters A and B are located, and then randomly one of the letters are considered as the drug group and the other letter as the control group. This method is referred to as "Permuted Blocked Randomization".
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Patients, radiologists and technicians who calculate pulse wave velocity are unaware of patients' 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**
Kashan University of Medical Sciences, Ghotb Ravandi St
**City**
Kashan
**Province**
Isfehan
**Postal code**
8115187159
**Approval date**
2020-02-17, 1398/11/28
**Ethics committee reference number**
IR.KAUMS.MEDNT.REC.1398.133

## Health conditions studied

### 1

**Description of health condition studied**
Diabetes
**ICD-10 code**
E11
**ICD-10 code description**
Type 2 diabetes mellitus

## Primary outcomes

### 1

**Description**
Carotid-femoral pulse wave velocity
**Timepoint**
Before intervention and 24 weeks after intervention
**Method of measurement**
Color doppler ultrasound

### 2

**Description**
Carotid Intima-media thickness
**Timepoint**
Before intervention and 24 weeks after intervention
**Method of measurement**
Color doppler ultrasound

## Secondary outcomes

### 1

**Description**

hs-CRP level

**Timepoint**

before and 24 weeks after intervention

**Method of measurement**

Blood test

## Intervention groups

### 1

**Description**

Intervention group: melatonin 5 mg (from NUTRALab), 2 capsules daily (half hour before sleep) for 24 weeks

**Category**

Treatment - Drugs

### 2

**Description**

Control group: placebo, 2 capsules daily (half hour before sleep) for 24 weeks

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Kashan Shahid Beheshti Hospital

**Full name of responsible person**

Mojtaba Ghasemi Adl

**Street address**

Shahid Beheshti Hospital, Ghotbe Ravandi Street

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Kashan

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8115187159

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+98 31 5562 1552

**Email**

beheshtihospital@kaums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Hamidreza Banafshe

**Street address**

Kashan University of Medical sciences, Ghotbe Ravandi Street

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**Email**

research@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**

Hamidreza Talari

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiology

**Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Position**

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## Person responsible for updating data

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**Fax**

**Email**

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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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available