

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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 mL/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 mL/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

Isfahan

##### 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  
**City**  
Kashan  
**Province**  
Isfahan  
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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  
**City**  
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**Province**  
Isfahan

**Postal code**  
8115187159  
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+98 31 5557 8010  
**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**  
Postal Code 81151/87159, Shahid Beheshti Hospital, Pezeshk Ave, Ravand Street  
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Isfahan  
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talari\_hr@kaums.ac.ir

## Person responsible for scientific inquiries

**Contact**  
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**Full name of responsible person**  
Hamidreza Talari  
**Position**

Professor  
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## Person responsible for updating data

### Contact

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Kashan University of Medical Sciences  
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**Postal code**  
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**Phone**  
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**Fax**  
**Email**  
talari\_hr@kaums.ac.ir

## 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