Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluating the effect of co-administration of melatonin and atorvastatin in type II diabetic patients with microalbuminuria

Protocol summary

Study aim

1. Comparison of effects of co-administration of atorvastatin and melatonin with atorvastatin and placebo on the ratio of urine albumin to creatinine in type-2 diabetic patients with microalbuminuria. 2. Comparison of effects of co-administration of atorvastatin and melatonin with atorvastatin and placebo on the rate of eGFR in type-2 diabetic patients with microalbuminuria.

Design

Randomised, parallel group trial with blinded outcome assessment. The sample size is120 patients. The random number table and block randomization method will be used for randomization.

Settings and conduct

Patients will be recruited from Firoozgar Hospital Endocrine Research Center. Patients who are eligible will sign informed consent form. Screening is done 30 days before treatment. Laboratory tests will be performed before the start of treatment and at 6 months after treatment. During the study, unwanted side effects will be investigated. Blood tests include serum creatinine, triglyceride, LDL-c, HDL-c, total cholesterol, fasting blood glucose, serum BUN. Urinalysis involves taking 24-hour urine and measuring urine volume, urine creatinine, urine albumin, and the ratio of urine albumin to creatinine and the rate of GFR. Patients, physicians, people who put medications in cans and data collection authorities will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type II diabetic patients with microalbuminuria. Patients who sign informed consent form. Patients with HbA1c < 8% Exclusion criteria: Patients with blood pressure > 160⁄90 mmHg Patients with statins intolerance. Pregnant or breast-feeding patients. Patients with a history of alcohol abuse or smoking.

Intervention groups

Group 1: Patients receiving atorvastatin (20 mg) and placebo. Group 2: Patients receiving melatonin (3 mg) and atorvastatin (20 mg) simultaneously.

Main outcome variables

Urine albumin to creatinine ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181118041689N1**
Registration date: **2018-11-24, 1397/09/03**
Registration timing: **prospective**

Last update: **2019-10-01, 1398/07/09**
Update count: **1**

Registration date

2018-11-24, 1397/09/03

Registrant information

Name

Azam Hosseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 3134

Email address

hoseinzadeh.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of co-administration of melatonin and atorvastatin in type II diabetic patients with microalbuminuria

Public title

The effect of melatonin and atorvastatin on diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type II diabetes Diabetic patient over 40 years of age. Patients with microalbuminuria (urinary albumin 30- 300 mg/24h) Patients who sign a written informed consent form. Patients with HbA1c of < 8%

Exclusion criteria:

Patients with blood pressure > 160/90 mmHg Patients with statins intolerance. Patients with statin-inducedmyopathy Patients who have used immunosuppressive drugs within 3 months of the first screening visit. Patients with intolerance to blood pressure reducing drugs (e.g., angiotensin II receptor-blocking drugs) Patients with other illness likely to influence the trial such as congestive heart failure, hypothyroidism, severe kidney failure, polycystic kidney disease, HIV nephropathy, ischemic kidney disease, interstitial nephritis of idiopathic kidney and hepatic failure Patients who have been kidney transplant in the past. Patients who have taken part in other clinical trials in the last 3 months. Patients who are pregnant or breast-feeding. Patients who are researchers and co-workers in this trial. Patients with a history of alcohol abuse or smoking.

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The random number table and block randomization method will be used using http://www.randomizer.org.In this method, eligible patients are divided into blocks of 4 patients. We create random numbers using computer.Based on the determined numerical range to enter individuals in each group, half of the patients in each block will receive atorvastatin (20 mg) and placebo and half of them receive atorvastatin (20 mg) and Melatonin (3 mg).

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, the person who puts the medication in cans and labels on the cans, the person who selects and enrols the eligible patients, A person who blocks patients and determines the allocation of medications to patients, the doctor who gives the medications to the patients, data collection authorities, those who evaluate the outcome and those who prepare the draft article do not know what kind of drugs are in each can.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-11-12, 1397/08/21

Ethics committee reference number

IR.IUMS.REC.1397.220

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus with kidney complication

ICD-10 code

E11.2

ICD-10 code description

Type 2 diabetes mellitus with kidney complications

Primary outcomes

1

Description

Urine albumin to creatinine ratio

Timepoint
Before the start of intervention and at 6 months after the start of treatment.
Method of measurement
Measuring creatinine and albumin levels in urine using biochemical tests.

Secondary outcomes

1

Description
Glomerular filtration rate (GFR)
Timepoint
Before the start of intervention and at 6 months after the start of treatment.
Method of measurement
The measurement is based on the results of blood creatinine, urine creatinine and 24-hour urine volume.

2

Description
Serum creatinine
Timepoint
Before the start of intervention and at 6 months after the start of treatment
Method of measurement
Using biochemical tests

3

Description
Blood triglyceride level
Timepoint
Before the start of intervention and at 6 months after the start of treatment
Method of measurement
Using biochemical tests

4

Description
Blood level of HDL cholesterol
Timepoint
Before the start of intervention and at 6 months after the start of treatment
Method of measurement
Using biochemical tests

5

Description
Blood level of LDL cholesterol
Timepoint
Before the start of intervention and at 6 months after the start of treatment
Method of measurement
Using biochemical tests

6

Description
Blood level of total cholesterol
Timepoint
Before the start of intervention and at 6 months after the start of treatment
Method of measurement
Using biochemical tests

7

Description
The level of fasting blood glucose
Timepoint
Before the start of intervention and at 6 months after the start of treatment
Method of measurement
Using biochemical tests

8

Description
The level of Blood Urea Nitrogen (BUN)
Timepoint
Before the start of intervention and at 6 months after the start of treatment
Method of measurement
Using biochemical tests

Intervention groups

1

Description
Control group: Patients with type II diabetes who have microalbuminuria and receive atorvastatin (20 mg) and placebo once a day for 6 months.
Category
Treatment - Drugs

2

Description
Intervention group: Patients with type II diabetes who have microalbuminuria and receive at the same time atorvastatin (20 mg) and Melatonin (3 mg) once a day for 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Institute of Endocrinology and Metabolism Research and Training Center
Full name of responsible person
Azam Hosseinzadeh
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Sponsors / Funding sources

1

Sponsor
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
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Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Informed consent form
When the data will become available and for how long
The start of the access period is 9 months after the publish of results.
To whom data/document is available
The data will only be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
People do not have any right to any analysis on the delivered data.
From where data/document is obtainable
Iran University of Medical Sciences, Razi Drug Research Center, Dr. Hosseinzadeh Email: Azam.hosseinzade@yahoo.com
What processes are involved for a request to access data/document
Apply to Vice Chancellor for Research & Technology of Iran University of Medical Sciences.
Comments