

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of oral melatonin administration with placebo on biochemical parameters associated with diabetes in diabetes mellitus Type 2 patients

Protocol summary

Study aim

The aim of present study is to determine whether adding melatonin tablet as adjuvant to diabetes treatment regimen in patients with type 2 diabetes will improve the glucose control with assessment of biochemical parameters associated with diabetes.

Design

Design of the study is a triple-blind, placebo-controlled, randomized control single center clinical trial. Patients with age more than 18 years old with type 2 diabetes have been diagnosed based on ADA (American Diabetes Association) 2017 guideline will be enrolled the study. Patients whom are not desired to enroll the study will be excluded. In this research, 80 eligible patients with type 2 diabetes compatible with inclusion criteria were chosen. patients were randomly divided into two control and intervention groups by Microsoft Excel software. and a code was allocated to each one of them.

Settings and conduct

This study is conducted as placebo controlled triple blinded randomized clinical trial in Shahid Beheshti research institute of endocrine science. participants, researcher & statistical data analyzer all has been blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetes based on ADA 2017 guideline Age more than 18 years old Exclusion criteria: History of confirmed hypersensitivity reaction to melatonin or any parts of formulation eGFR less than 30 ml/min/1.73m² Liver failure (child pugh B, C) Pregnancy & lactation Uncontrolled seizure & untreated major depressive disorder Concurrent use of fluvoxamine & nifedipine

Intervention groups

Intervention group (melatonin supplement): type 2 dietetic patients compatible with inclusion/exclusion criteria on any diabetes treatment regimens

administrated with 6 mg oral melatonin supplement daily for 2 mouths. Control group (melatonin placebo): type 2 dietetic patients compatible with inclusion/exclusion criteria on any diabetes treatment regimens administrated with 6 mg oral melatonin placebo daily for 2 mouths.

Main outcome variables

Change in blood level of FBS, HgbA1c, HOMA-IR, HOMA-beta, lipid profile, hs-CRP and melatonin 2 months after initiation of melatonin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121021011192N4**

Registration date: **2018-01-06, 1396/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-06, 1396/10/16**

Update count: **0**

Registration date

2018-01-06, 1396/10/16

Registrant information

Name

Mohammad Abbasinazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral melatonin administration with placebo on biochemical parameters associated with diabetes in diabetes mellitus Type 2 patients

Public title

Melatonin in type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes based on ADA (American Diabetes Association) 2017 guideline Age more than 18 years old

Exclusion criteria:

History of confirmed hypersensitivity reaction to melatonin or any parts of formulation eGFR less than 30 ml/min/1.73m² Liver failure (child pugh B, C) Pregnancy & lactation Uncontrolled seizure & untreated major depressive disorder Concurrent use of fluvoxamine & nifedipine

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 88

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with Microsoft Excel software

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, principle investigator, healthcare providers (Physicians, nurses) who care for participants during the trial, data collectors and outcome assessors all are blinded by providing placebo melatonin in same size, shape color, odor and package with real melatonin tablet which organized just by one responsible co-researcher

has no involvement in running study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Research Institute for Endocrine Sciences Shahid Beheshti University of Medical

Street address

No.24 Arabi str., Daneshju Blvd., Yemen str., Velenjak

City

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Postal code

1985717413

Approval date

2017-07-15, 1396/04/24

Ethics committee reference number

IR.SBMU.ENDOCRINE.REC.1396.424

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Change in hemoglobin A1C serum level

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

2

Description

Change in fasting blood sugar level

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

3

Description

Change in percent of HOMA_IR

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

4

Description

Change in percent of HOMA_Beta

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

5

Description

Change in melatonin serum level

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

6

Description

Change in total cholesterol serum level

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

7

Description

Change in total L.D.L cholesterol serum level

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

8

Description

Change in total H.D.L cholesterol serum level

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

9

Description

Change in total triglyceride serum level

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

10

Description

Change in total high sensitivity CRP serum level

Timepoint

Before intervention and 60 -80 days after initiation of daily use of melatonin

Method of measurement

Lab kits

Secondary outcomes

1

Description

Record of Adverse drug reactions

Timepoint

During intervention

Method of measurement

Interview with patients

Intervention groups

1

Description

Intervention group: Addition of melatonin tablet orally 6 mg/d to for 2 weeks Type 2 diabetes regimen for 2 months

Category

Treatment - Drugs

2

Description

Control group: Addition of melatonin placebo tablet orally 6 mg/d to for 2 weeks Type 2 diabetes regimen for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute for Endocrine Sciences Shahid Beheshti University of Medical

Full name of responsible person

Farzad Hadaegh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nima Naderi

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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

Deputy of Research, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

25

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

2

Sponsor

Name of organization / entity

Deputy of Research, Research Institute for Endocrine Sciences Shahid Beheshti University of Medical

Full name of responsible person

Maryam Tohidi

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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

Deputy of Research, Research Institute for Endocrine Sciences Shahid Beheshti University of Medical

Proportion provided by this source

75

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

Deputy of research, School of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nima Naderi

Position

Ph.D in Toxicology

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

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Contact

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Full name of responsible person

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Position

clinical pharmacy specialist

Latest degree

Specialist

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clinical pharmacist

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Full name of responsible person

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Latest degree

Subspecialist

Other areas of specialty/work

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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