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

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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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Province
Tehran
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 suger 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 Universty 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 Universty 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
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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 Beheshty Universiti 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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Position
clinical pharmacy specialist

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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