

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of melatonin on serum glucose level in patients with type 2 diabetes

Protocol summary

Summary

Aim of this study is evaluation of melatonin effect on blood glucose in patients with type 2 diabetes. The study is double-blind and randomized and 60 patients recruited in two groups. One group consume 6 mg melatonin and second group receive placebo for three months. Before and after intervention blood glucose, A1C and lipids are measured. Patients with epilepsy, renal or liver failure and who use warfarin are excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010520219N2**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

Name

Mozhgan Afkhamizadeh

Name of organization / entity

Mashhad University of Medical Sciences , Imam Reza Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 8818

Email address

afkhamizadehm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-09-05, 1395/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin on serum glucose level in patients with type 2 diabetes

Public title

Effect of melatonin on diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : type 2 diabetes; FBS less than 250
exclusion criteria : renal failure; hepatic failure; epilepsy; pregnancy; breast feeding; warfarin consumption; psychotic disease

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

research chancellor, Mashhad university of medical sciences, Daneshgah St.

City

Mashhad

Postal code

91388-13944

Approval date

2015-11-18, 1394/08/27

Ethics committee reference number

IR. MUMS. fm. REC. 1394.479

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

fasting blood glucose

Timepoint

before and after intervention

Method of measurement

laboratory measurement (mg/dl)

Secondary outcomes

1

Description

serum lipids

Timepoint

before and three months after intervention

Method of measurement

laboratory (mg/dl)

Intervention groups

1

Description

intervention: melatonin 6 mg

Category

Treatment - Drugs

2

Description

control : placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital ,Mashhad Endocrine Research Center

Full name of responsible person

Mozhgan Afkhamizadeh

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Aliakbar Saber Moghadam

Street address

Research chancellor, MashhadUniversity of Medical Sciences, Daneshgah St.

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashad University of Medical Sciences

Full name of responsible person

Mozhgan Afkhamizadeh

Position

Assisitan professor

Other areas of specialty/work**Street address**

Internal medicine department, Imam Reza Hospital

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Person responsible for updating data

Contact

Name of organization / entity**Full name of responsible person**

Mozhagn Afkhamizadeh

Position**Other areas of specialty/work****Street address****City****Postal code****Phone**

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Fax**Email****Web page address**

Sharing plan

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad Endocrine and Metabolism Research Centre,

Mashhad University of Medical Sciences

Full name of responsible person

Mozhgan Afkhamizadeh

Position

endocrinologist

Other areas of specialty/work**Street address**

Internal medicine department, Imam Reza hospital

City

Mashhad

Postal code**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty