Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effects of melatonin on glucose and lipids profile in type II diabetic patients

Protocol summary

Summary

The aim of this double blind placebo controlled clinical trial is to investigate the effects of melatonin on glucose and lipids profile in type II diabetic patients. This study will be conducted as a before and after design and 76 patients who have inclusion criteria (diabetes mellitus type II, serum Cr<2mg/dl, HbA1c<8.5%) will receive placebo 2 tab/day for 12 weeks and then melatonin 6mg/day for another 12 weeks. Exclusion criteria will be melatonin consumption, pregnancy or breast feeding, current or history of epilepsy, smoking, drug addiction, alcohol or amphetamine abuse, warfarin or nifidipin medication, shifting job, history of coagulopathy or bleeding, change in diabetic or anti lipid treatment protocol, starting treatment by beta-blockers or diuretics. FBS and lipid profile will be measured in first evaluation and weeks 12 and 24.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012062610115N1**
Registration date: **2012-07-06, 1391/04/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-07-06, 1391/04/16

Registrant information

Name
Gila Heshmati
Name of organization / entity
Arak university of medical sciences
Country
Iran (Islamic Republic of)
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+98 86 1223 5605
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Arak University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-05-20, 1391/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of melatonin on glucose and lipids profile in type II diabetic patients

Public title

The effects of melatonin on glucose and lipids profile in type II diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diabetes mellitus type II; serum Cr <2 mg/dl; HbA1c <8.5%. Exclusion criteria: melatonin consumption; pregnancy or breast feeding; current or history of epilepsy; smoking; drug addiction; alcohol or amphetamine abuse; warfarin or nifidipin medication; shifting job; history of coagulopathy or bleeding; change in diabetic or anti lipid treatment protocol; starting treatment by beta-blockers or diuretics.

Age

No age limit

Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Arak university of medical sciences
Street address
Arak university of medical sciences, Sardasht
City
Arak
Postal code
Approval date
2011-12-25, 1390/10/04
Ethics committee reference number
90-118-5

Health conditions studied

1

Description of health condition studied
diabetes mellitus type2
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Fasting Blood Suger
Timepoint
weeks 0,12,24
Method of measurement
laboratory

2

Description
lipid profile
Timepoint
weeks 0,12,24
Method of measurement
laboratory

3

Description
HbA1c (%)
Timepoint
weeks 0,12,24
Method of measurement
laboratory

Secondary outcomes

empty

Intervention groups

1

Description
intervention: tab melatonin 3mg, 2 tab /day for 12 weeks
Category
Treatment - Drugs

2

Description
control: placebo, 2 tab/day for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Almomenin hospital
Full name of responsible person
Street address
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak university of medical sciences
Full name of responsible person
Dr. Saeed Changizi Ashtyani
Street address

Arak university of medical sciences, Sardasht

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak university of medical sciences

Full name of responsible person

Dr. Glare Heshmati

Position

resident of internal medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mohammad Reza Rezvanfar

Position

Endocrinologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Arak university of medical sciences

Full name of responsible person

Dr. Akram Esmaili

Position

GP

Other areas of specialty/work

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Sharing plan

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