

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 nifedipin 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)

Phone

+98 86 1223 5605

Email address

dr.heshmati@arakmm.ac.ir

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 nifedipin 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 Sugar

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

Street address

Amir almomenin hospital, Arak University of Medical Sciences

City

Arak

Postal code

Phone

+98 86 1223 5605

Fax

Email

dr.heshmati@arakMM.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak university of medical sciences

Full name of responsible person

Dr. Mohammad Reza Rezvanfar

Position

Endocrinologist

Other areas of specialty/work

Street address

Vali asr hospital, Arak University of Medical Sciences

City

Arak

Postal code

Phone

+98 86 1222 2004

Fax

Email

daesmaili@gmail.com

Web page address

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

Street address

Arak university of medical sciences

City

Arak

Postal code

Phone

+98 86 1223 5605

Fax

Email

daesmaili@gmail.com

Web page address

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