

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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**Phone**

+98 86 1223 5605

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**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**

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Vali asr hospital, Arak University of Medical Sciences

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daesmaili@gmail.com

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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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**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*