

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Determination of the effect of melatonin supplement on the activity of antioxidant enzymes in prediabetes patients

#### Protocol summary

##### Summary

Determination of the effect of melatonin supplement on the activity of antioxidant enzymes in the prediabetic patients. The research is a randomized clinical trial. 70 prediabetic patients will participate in the study and will be randomly divided into two groups. At the first meeting the purpose of study will be described and asked them to fill the consent form. Group 1 will receive 30,3 mg melatonin tab for 30 days and group 2 will receive 30 placebo tab(same shape, colour, size) for 30 days and asked them to take tabs before bed time . Patients will be followed in these 30 days. The height, weight and blood pressure of the patients will record before and after the intervention and fasting blood will be collected and stored at -80 (c) refrigerator. The leves of FBS, SOD,CAT,TAC will be measured before the melatonin treatment and at least 30 days after the initiation of the treatment. In addition, a 24-h recall and a physical activity questionnaire will be completed by subjects before the melatonin treatment and at least 30 days after the initiation of the treatment. Including criteria fasting blood in the range of 100-125. Age between 35 and 50 - BMI  $\geq$  25 kg/m<sup>2</sup> - Having normal physical activities. Excluding criteria- Changing drug diet - Adopting special diets - Ceasing intake of the supplement for three days.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012110411361N1**  
Registration date: **2012-12-15, 1391/09/25**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-12-15, 1391/09/25

##### Registrant information

###### Name

Azam Mohebi

###### Name of organization / entity

Public Health Department of Tehran University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4427 4674

###### Email address

a-mohebi@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2012-06-21, 1391/04/01

##### Expected recruitment end date

2012-12-21, 1391/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determination of the effect of melatonin supplement on the activity of antioxidant enzymes in prediabetes patients

##### Public title

effect of melatonin supplement on oxidative stress

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Requirements to select patients: The patients whose affliction with prediabetes are confirmed and their blood

sugar before breakfast is in the range of 100-125;age between 35 and 50;BMI  $\geq$  25 kg/m<sup>2</sup>;Having normal physical activities ;Interested in the research project Factors preventing patients from being included in the study ,Smoking, and using alcohol and other drugs ;Professional athletes ,Persons used the drugs reducing blood lipid, heart drugs, hypertension drugs, diuretics, vitamin supplements or any antioxidant three months before the intervention ,Using anti-inflammatory drugs, the drugs or materials having interference with melatonin supplement, such as vafarin, within three months before the intervention ;Having a record of ischemic heart disease, stroke, kidney failure, cancer, chemotherapy, radiotherapy and other diseases in which free radicals are a cause ;Women in the period of pregnancy and breastfeeding;Women with premature menopause;People working at night shifts ;People engaged in shift working Removing patients from the population:Changing drug diet ;Adopting special diets;Ceasing intake of the supplement for three days

#### Age

From **35 years** old to **50 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

#### 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

Tehran University of Medical Sciences

##### Street address

16 Azar st, Poursina st, Keshavarz blv

##### City

Tehran

##### Postal code

#### Approval date

2012-04-15, 1391/01/27

#### Ethics committee reference number

62789

## Health conditions studied

### 1

#### Description of health condition studied

prediabetes

#### ICD-10 code

R73.0

#### ICD-10 code description

Abnormal glucose tolerance test

## Primary outcomes

### 1

#### Description

activity of SOD enzyme

#### Timepoint

befor intervention,1 month after intervention

#### Method of measurement

blood test,U/gHb,kit

### 2

#### Description

activity of CAT enzyme

#### Timepoint

befor intervention,1 month after intervention

#### Method of measurement

blood test,k/gHb,kit

### 3

#### Description

TAC serum

#### Timepoint

befor intervention,1 month after intervention

#### Method of measurement

blood test,Mmol/ml,kit

## Secondary outcomes

### 1

#### Description

blood pressure

#### Timepoint

befor intervention,1 month after intervention

#### Method of measurement

Sphygmomanometer,mmHg

### 2

#### Description

fasting blood sugar

#### Timepoint

befor intervention,1 month after intervention

#### Method of measurement

blood test,Mg/dl

### 3

**Description**

height

**Timepoint**

before intervention

**Method of measurement**

stadiometer,cm

### 4

**Description**

weight

**Timepoint**

before intervention,30 days after intervention

**Method of measurement**

Scale ,kg

### 5

**Description**

BMI

**Timepoint**

before intervention,30 days after intervention

**Method of measurement**

calculate, kg/cm<sup>2</sup>

## Intervention groups

### 1

**Description**

intervention group:melatonin supplement 3mg for 1 month before sleep

**Category**

Prevention

### 2

**Description**

control group: corn starch placebo before sleep

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

14 Masum Health Center

**Full name of responsible person**

Dr Sarvi

**Street address**

Rezvan alley, Sobhani st, Ghazvin st

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Vice-chancellor for research -Tehran University of Medical Science

**Full name of responsible person**

Dr Saedi Ahmad

**Street address**

Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for research -Tehran University of Medical Science

**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**

Department of Nutrition and Biochemistry

**Full name of responsible person**

Azam Mohebi

**Position**

Master of nutritional science

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

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## Person responsible for scientific inquiries

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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*