

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effects of melatonin supplementation on nutritional status, oxidative stress, metabolic and inflammatory parameters in obese women undergoing weight loss diet

#### Protocol summary

##### Summary

In a double-blind randomized clinical trial 46 volunteer obese women will be recruited. Subjects will be randomly assigned into melatonin and placebo groups based on Permuted block randomization using the SAS software. Concurrent with weight loss diet two groups will receive daily 6 mg melatonin or 6 mg placebo 2 hours before bed time for 40 days. General information and dietary intake of subjects will be collected by questionnaire and 24-hour dietary recall method respectively. After measuring of weight, height, waist and hip circumference, body mass index and waist to hip ratio will be calculated. After overnight fasting 10 ml blood samples will be collected. Serum glucose, insulin, leptin ,adiponectin, inflammatory and oxidative stress factors and lipid profiles will be determined at baseline and endpoint of the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012122411867N1**

Registration date: **2013-07-01, 1392/04/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-07-01, 1392/04/10

##### Registrant information

##### Name

Naimeh Mesri Alamdari

##### Name of organization / entity

Faculty of Health and Nutrition, Tabriz University Of  
Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

##### Email address

mesri65@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Nutrition Research Center, Tabriz University of Medical  
Sciences

##### Expected recruitment start date

2013-05-22, 1392/03/01

##### Expected recruitment end date

2013-09-21, 1392/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of melatonin supplementation on nutritional status, oxidative stress, metabolic and inflammatory parameters in obese women undergoing weight loss diet

##### Public title

The effect of melatonin supplementation on obesity management

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Volunteer women with body mass index(BMI) =30 or more, aged between 20-50 years with maintained weight during the last six months Exclusion criteria: Include pregnancy and lactation, menopause, smoking, alcohol consumption, having endocrine or kidney disease, depression, taking tranquilizers,

contraceptives, anti-inflammatory, glucose and lipid-lowering drugs. Also taking any kind of antioxidant supplements in the last 3 months

**Age**

From **20 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

A double-blind procedure is used to prevent both experimenter bias and placebo effects.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University Of Medical Sciences

**Street address**

Vice-chancellor for Research, Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code****Approval date**

2013-04-15, 1392/01/26

**Ethics committee reference number**

Letter No: 612/4/5 Ethic code : 924

**Health conditions studied****1****Description of health condition studied**

obesity

**ICD-10 code**

E66.0

**ICD-10 code description**

Obesity due to excess calories

**Primary outcomes****1****Description**

adiponectin

**Timepoint**

The onset and end of the study

**Method of measurement**

ELISA

**2****Description**

Glucose

**Timepoint**

The onset and end of the study

**Method of measurement**

Enzymatic colorimetric

**3****Description**

Insulin

**Timepoint**

The onset and end of the study

**Method of measurement**

Chemiluminescence

**4****Description**

high sensitive c- reactive protein

**Timepoint**

the onset and end of the study

**Method of measurement**

immunospectrometry

**5****Description**

leptin

**Timepoint**

The onset and end of the study

**Method of measurement**

ELISA

**6****Description**

Nutritional status

**Timepoint**

The onset and end of the study

**Method of measurement**

Measurement of energy and nutrients intake using 24-hour dietary recall method and anthropometric measurement using scale and stadiometer

**7****Description**

Total antioxidant capacity

**Timepoint**

The onset and end of the study  
**Method of measurement**  
Spectrophotometry

## 8

### **Description**

LDL-C

### **Timepoint**

The onset and end of the study

### **Method of measurement**

Enzymatic colorimetric

## 9

### **Description**

Total cholesterol

### **Timepoint**

The onset and end of the study

### **Method of measurement**

Enzymatic colorimetric

## 10

### **Description**

Malondialdehyde

### **Timepoint**

The onset and end of the study

### **Method of measurement**

Spectrophotometry

## 11

### **Description**

HDL-C

### **Timepoint**

The onset and end of the study

### **Method of measurement**

Enzymatic colorimetric

## 12

### **Description**

Triglyceride

### **Timepoint**

The onset and end of the study

### **Method of measurement**

Enzymatic colorimetric

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: melatonin which is a natural hormone in the body and regulates sleep will be administered as oral supplement at a dose of 6 milligram (2 melatonin tablet, 3 mg each; made by Nature Made, USA) 2 hours before bed time for 40 days with weight

loss diet.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group will receive 6 mg placebo ( 2 tablet, 3 mg each containing cellulose, silicon dioxide and starch) 2 hours before bed time for 40 days with weight loss diet.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

The Clinics of Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr. Reza Mahdavi

##### **Street address**

Faculty of Health and Nutrition, Tabriz University of Medical Sciences

##### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice-Chancellor for Research, Tabriz University of Medical Sciences- Nutrition Research Center

##### **Full name of responsible person**

Dr. Alireza Ostadrahimi

##### **Street address**

Faculty of Health and Nutrition, Tabriz University Of Medical Sciences

##### **City**

Tabriz

#### **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, Tabriz University of Medical Sciences- Nutrition Research Center

#### **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**

Faculty of Health and Nutrition, Tabriz University Of  
Medical Sciences

**Full name of responsible person**

Dr. Alireza Ostadrahimi

**Position**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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**Postal code****Phone****Fax****Email****Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Faculty of Health and Nutrition, Tabriz University of  
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**Full name of responsible person**

Dr. Reza Mahdavi

**Position**

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

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street, Golgasht street, Tabriz

**City**

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**Postal code**

5166614711

## 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*