

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of melatonin supplementation on weight and depression among overweight women with depression compared with the control group

#### Protocol summary

##### Summary

- Objective: To determine the effects of melatonin supplementation on weight and depression among overweight women with depression compared with the control group. - Main inclusion criteria: Age 18 to 50 years, female gender, body mass index above 25, the diagnosis of depression - Main exclusion criteria: Taking drugs that affect on depression and weight, hormonal and metabolic disorders - Study population: The 18-50 years women with depression who are overweight or obese - Sample size: 50 - Intervention Study: Melatonin - Intervention duration: 12 weeks - Primary outcome or outcomes studied: Depression, weight, body mass index - Design of the study: fifty patients with mild depression (based on a semi-structured diagnostic interview and the Hamilton depression scale test) who are overweight or obese will participate in this double-blind, 12-week, placebo-controlled study. Participants will sign the informed consent form and then they will be randomly assigned to one of two groups receiving daily 6 mg of melatonin capsules (two 3 mg capsules one hour before bedtime) or placebo. The groups will be blinded by placebo to participants and will be blinded to researcher by coding. At the end, hypothesis of the study will be tested.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014020316465N1**

Registration date: **2014-05-19, 1393/02/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-05-19, 1393/02/29

#### Registrant information

##### Name

Seyed-Ali Mostafavi

##### Name of organization / entity

Psychiatry Research Center/ Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5542 2002

##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2014-08-23, 1393/06/01

#### Expected recruitment end date

2016-02-20, 1394/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effects of melatonin supplementation on weight and depression among overweight women with depression compared with the control group

#### Public title

Evaluating the effects of melatonin on weight and depression

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 50 years; females; Body Mass Index above 25; patients with mild (minor)

depression based on semi- structured diagnostic interview by a psychiatrist; to sign a consent form  
Exclusion Criteria: Those who are taking antidepressants; severe (major) depression; psychotic depression or have suicidal thoughts; use of anti-inflammatory glucocorticoids, and steroids; those who take medicines to reduce appetite or weight; those with diabetes who are taking medications or insulin; those with heart disease or hypercholesterolemia who are taking medication (statins, fibrates, diuretics); those how are taking oral anti-inflammatory drugs corticosteroids or any drug that causes weight loss or gain; taking hormonal contraceptives; pregnancy and lactation; menopause; severe mental disorder; schizophrenia and bipolar; hypothyroidism; exercise professionals; allergic to fish (due to Omega-3 supplements); those with special diets such as the diets for kidney disorders.

**Age**

From **18 years** old to **50 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**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**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Committee on Ethics in Medical Research, Research Council, Central Building of Tehran University of Medical Sciences, Keshavarz Blvd Tehran, Iran

**City**

Tehran

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

2010-12-05, 1389/09/14

**Ethics committee reference number**

130/2045/92/3

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

Mild Depression

**ICD-10 code**

F32.0

**ICD-10 code description**

Mild depressive episode Two or three of the above symptoms are usually present. The patient is usually distressed by these but will probably be able to continue with most activities.

**2****Description of health condition studied**

Moderate depression

**ICD-10 code**

F32.1

**ICD-10 code description**

Moderate depressive episode Four or more of the above symptoms are usually present and the patient is likely to have great difficulty in continuing with ordinary activities.

**3****Description of health condition studied**

Obesity

**ICD-10 code**

E66.0

**ICD-10 code description**

Obesity due to excess calories

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

weight

**Timepoint**

at baseline and at weeks 2, 4, 8 and 12 after the beginning of the study

**Method of measurement**

Standard scales Seca

**2****Description**

Body Mass Index

**Timepoint**

at baseline and at weeks 2, 4, 8 and 12 after the beginning of the study

**Method of measurement**

kg/(m)<sup>2</sup>

**3****Description**

Depression

**Timepoint**

At baseline and at weeks 2, 4, 8 and 12 after the beginning

of the study

**Method of measurement**

Hamilton rating scale for depression

**Secondary outcomes**

**1**

**Description**

Central fat mass

**Timepoint**

At baseline and at weeks 2, 4, 8 and 12 after the bigining

**Method of measurement**

Bioelectrical impadance

**2**

**Description**

Side effects

**Timepoint**

At the last seccion

**Method of measurement**

Side effect questionnaire

**Intervention groups**

**1**

**Description**

6 mg melatonin capsules (two 3 mg capsules one hour before bedtime) for 12 weeks

**Category**

Treatment - Drugs

**2**

**Description**

Two placebo capsules for 12 weeks

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Private weight loss clinic

**Full name of responsible person**

**Street address**

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Harati-Zadeh

**Street address**

No 608, Research Coordination Centre Office, Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Boulevard

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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**

Psychiatry Research Center

**Full name of responsible person**

Seyed-Ali Mostafavi

**Position**

PhD by Research student

**Other areas of specialty/work**

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Roostbeh Hospital, South Kargar St.

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## Person responsible for updating data

### Contact

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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*