Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Psychiatry Research Center/ Tehran University of Medical Sciences
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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/د

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
Obseity

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 bigining 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 bigining of the study

Method of measurement
kg/(m)2

3

Description
Depression

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

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 secsion

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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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