

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Investigating the effect of melatonin supplementation on plasma levels of ghrelin, 2-arachidonoylglycerol and hedonic eating intensity

Protocol summary

Study aim

To determine the effect of melatonin supplementation on plasma levels of ghrelin, 2-arachidonoylglycerol and hedonic eating intensity

Design

Parallel, double-blind, randomized clinical trial with control group, on 46 patients. Random allocation software (RAS) will be used for random allocation.

Settings and conduct

The study will be conducted in Tabriz University of Medical Sciences, Faculty of Nutrition and Food Sciences in 46 eligible volunteers with high hedonic eating intensity (23 participants in the melatonin and 23 in the placebo group). Participants in both groups will take a 5 mg melatonin or a placebo tablet, one hour before going to bed at night for 8 weeks. The plasma levels of acyl ghrelin and 2-arachidonoylglycerol will be measured in the fasting state prior the start of the intervention and after 8 weeks. Also, 3-day food recall and Power of Food Scale will be used to measure the impact of the intervention on food intake and hedonic eating intensity. The study will be double-blind, neither the researcher nor the participants will be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy obese or overweight 19 to 49 years women with high hedonic eating intensity

Exclusion Criteria: Postmenopausal, pregnant or lactating women, Suffering from substance abuse and alcohol addiction, Using drugs affecting appetite, Using medications that interfere with melatonin

Intervention groups

Participants in both groups will take a 5 mg melatonin or placebo tablet, one hour before going to bed at night for 8 weeks.

Main outcome variables

Nutritional status (total energy intake, energy intake from macronutrients, and weight) Plasma levels of acyl ghrelin and 2-arachidonoylglycerol Hedonic eating score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080904001197N22**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

Reza Mahdavi

Name of organization / entity

Faculty of Health & Nutrition, Tabriz Univ. of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-09-19, 1403/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of melatonin supplementation on plasma levels of ghrelin, 2-arachidonoylglycerol and hedonic eating intensity

Public title

Investigating the effect of melatonin supplementation in obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Apparently healthy women volunteers Literate 19-49 years BMI=25-34.9 kg/m² Having high hedonic eating intensity Unwillingness to diet Desire to use drugs or supplements to lose weight

Exclusion criteria:

Postmenopausal, pregnant or lactating women Recent weight loss or participation in weight loss programs Suffering from binge eating Current smokers Recent history of taking supplements affecting appetite (in the last 3 months) Women who, according to themselves, are suffering from substance abuse, alcohol addiction, certain diseases such as cancer, heart disease and diabetes Women who, according to themselves, have hypothyroidism and use medicine for this purpose Women who, according to themselves, use drugs that affect appetite, such as antidepressants, steroids, and contraceptives Having night shifts Having severe insomnia or thyroid disorders Using drugs that interfere with melatonin (anti-hypertensive drugs, anticonvulsant drugs, beta blockers, anticoagulant drugs, sedatives, antidepressants, oral contraceptive pill, corticosteroids) Melatonin supplementation intolerance during the study Using less than 90% melatonin supplements or placebo

Age

From **19 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be randomly allocated to either the melatonin or placebo groups in a 1:1 ratio using the Random Allocation Software (RAS), through the Stratified Blocked Randomization method (in blocks of 2) stratified by BMI (< 30 kg/m² or ≥ 30 kg/m²) as the possible confounding factor.

Blinding (investigator's opinion)

Double blinded

Blinding description

To conduct a double-blind study, at the beginning of the study, the packages containing melatonin and placebo supplements will be coded as A and B by a person not

involved in the study (to blind the researcher). Also, the supplement and placebo pills will be identical in terms of color, shape, smell and appearance (to blind the participant).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah street

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East Azarbaijan

Postal code

5166614776

Approval date

2023-04-17, 1402/01/28

Ethics committee reference number

IR.TBZMED.REC.1402.075

Health conditions studied

1

Description of health condition studied

Overweight and Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Plasma level of acyl ghrelin

Timepoint

Before starting and at the end of the study

Method of measurement

ELISA

Secondary outcomes

1

Description

Plasma level of 2-arachidonylglycerol

Timepoint

Before starting and at the end of the study

Method of measurement

ELISA

2

Description

Hedonic eating score

Timepoint

The first phase of the study and at the end of the study

Method of measurement

Power of food scale

3

Description

Total energy intake

Timepoint

Before the start of the study, after 4 weeks, and at the end of the study

Method of measurement

3-day food recall

4

Description

Energy intake from macronutrients

Timepoint

Before the start of the study, after 4 weeks, and at the end of the study

Method of measurement

3-day food recall

5

Description

Weight

Timepoint

Before the start of the study, after 4 weeks, and at the end of the study

Method of measurement

Scale

Intervention groups

1

Description

Intervention group: Participants in this group will take a 5 mg melatonin tablet one hour before going to bed at night with enough water for 8 weeks.

Category

Treatment - Other

2

Description

Control group: Participants in this group will take a 5 mg

placebo tablet (combination of silicon dioxide, cellulose and starch) one hour before going to bed at night with enough water, for 8 weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available