Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Reza Mahdavi
Name of organization / entity
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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
City
Tabriz
Province
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
Malihe Karamizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Malihe Karamizadeh

Position

Ph.D Student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Professor

Latest degree

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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