

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Effect of Melatonin supplementation on Body Weight, Body Fat Mass percentage and Body Mass Index changes in overweight or class-1 obese people

Protocol summary

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Summary

The aim of the present study is to determine the effect of Melatonin supplementation on body weight, Body Mass Index (BMI), and body fat percentage of people with overweight or class-I obesity. Target society of the study is the overweight and obese population. 38 overweight or class-I obese adult people will participate in the study. Participants will randomly be assigned to one of the two following groups: intervention or comparison. Patients will receive 3 milligram Melatonin or its placebo per day for 12 weeks in the intervention group and comparison group; respectively. Primary outcomes of this study are body weight, body mass index, and body fat percentage.

Recruitment status

Recruitment complete

Funding source

National Nutritional Research Institute

Expected recruitment start date

2012-08-26, 1391/06/05

Expected recruitment end date

2015-03-05, 1393/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020120891N1**

Registration date: **2015-02-09, 1393/11/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-09, 1393/11/20

Registrant information

Name

Salman Mohammadi

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3340 8176

Email address

Scientific title

Effect of Melatonin supplementation on Body Weight, Body Fat Mass percentage and Body Mass Index changes in overweight or class-1 obese people

Public title

Effect of Melatonin supplementation on obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria (BMI between 25-35; Age between 19 and 55 years) Exclusion criteria (to be afflicted by thyroid dysfunctions and diabetes mellitus; consumption of drugs affecting body weight and body fat mass; to be afflicted by polycystic ovary syndrome and cushing syndrome; consumption of corticosteroids, anti-depression drugs, contraceptive drugs, anti convulsion drugs and drugs affecting sleep pattern; consumption of alcohol; to be in the periods of pregnancy or lactation)

Age

From **19 years** old to **55 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 38

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
National Nutritional research Institute

Street address
Next to Arike Iranian, Arghavan gharbi St, Shahrake gharb

City
Tehran

Postal code
6841836118

Approval date
2012-07-31, 1391/05/10

Ethics committee reference number
046461

Health conditions studied

1

Description of health condition studied
Overweight or obesity

ICD-10 code
E66

ICD-10 code description
Obesity

Primary outcomes

1

Description
Body weight

Timepoint
Baseline, 45 days after baseline, 3 months after baseline

Method of measurement
Weighing by weight scale

2

Description
Body fat mass percentage

Timepoint
Baseline, 45 days after baseline, 3 months after baseline

Method of measurement
BIA

Secondary outcomes

1

Description
Sleep hours

Timepoint
Baseline, 45 days after baseline, 3 months after baseline

Method of measurement
Questionnaire

2

Description
Salivary Melatonin level

Timepoint
Baseline, 3 months after baseline

Method of measurement
ELISA kit

Intervention groups

1

Description
Intervention group (Melatonin, 3 milligrams, oral tablet, one tablet per day for 3 months)

Category
Treatment - Drugs

2

Description
Control group (Placebo, oral tablet, one tablet per day for 3 months)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Diet Therapy Clinic

Full name of responsible person
Mr Salman mohammadi

Street address
Next to Arike Iranian, Arghavan gharbi St, Shahrake gharb

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Nutritional Research Institute
Full name of responsible person
Mrs Masomeh Arabzadeh
Street address
Next to Arike Iranian, Shahrake gharb
City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source

National Nutritional Research Institute

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
Lorestan University of Medical Sciences
Full name of responsible person
Salman Mohammadi
Position
Faculty member
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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