Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 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

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 recieve 3 milligram Melatonin or its placebo per day for 12 weeks in the intervention group and comparison group; respectively. Primary outcoms of this study are body weight, body mass index, and body fat percentage.

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
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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

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 corticostroids, anti-depresssion drugs, contraceptive drugs, anti convulsion dugs 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
Questionnare

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 Masoomeh Arabzadeh
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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
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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