

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effects of melatonin supplementation on nutritional status, oxidative stress, metabolic and inflammatory parameters in obese women undergoing weight loss diet

Protocol summary

Summary

In a double-blind randomized clinical trial 46 volunteer obese women will be recruited. Subjects will be randomly assigned into melatonin and placebo groups based on Permuted block randomization using the SAS software. Concurrent with weight loss diet two groups will receive daily 6 mg melatonin or 6 mg placebo 2 hours before bed time for 40 days. General information and dietary intake of subjects will be collected by questionnaire and 24-hour dietary recall method respectively. After measuring of weight, height, waist and hip circumference, body mass index and waist to hip ratio will be calculated. After overnight fasting 10 ml blood samples will be collected. Serum glucose, insulin, leptin ,adiponectin, inflammatory and oxidative stress factors and lipid profiles will be determined at baseline and endpoint of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122411867N1**

Registration date: **2013-07-01, 1392/04/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-07-01, 1392/04/10

Registrant information

Name

Naimeh Mesri Alamdari

Name of organization / entity

Faculty of Health and Nutrition, Tabriz University Of
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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Nutrition Research Center, Tabriz University of Medical
Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of melatonin supplementation on nutritional status, oxidative stress, metabolic and inflammatory parameters in obese women undergoing weight loss diet

Public title

The effect of melatonin supplementation on obesity management

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Volunteer women with body mass index(BMI) =30 or more, aged between 20-50 years with maintained weight during the last six months Exclusion criteria: Include pregnancy and lactation, menopause, smoking, alcohol consumption, having endocrine or kidney disease, depression, taking tranquilizers,

contraceptives, anti-inflammatory, glucose and lipid-lowering drugs. Also taking any kind of antioxidant supplements in the last 3 months

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

A double-blind procedure is used to prevent both experimenter bias and placebo effects.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University Of Medical Sciences

Street address

Vice-chancellor for Research, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2013-04-15, 1392/01/26

Ethics committee reference number

Letter No: 612/4/5 Ethic code : 924

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

adiponectin

Timepoint

The onset and end of the study

Method of measurement

ELISA

2

Description

Glucose

Timepoint

The onset and end of the study

Method of measurement

Enzymatic colorimetric

3

Description

Insulin

Timepoint

The onset and end of the study

Method of measurement

Chemiluminescence

4

Description

high sensitive c- reactive protein

Timepoint

the onset and end of the study

Method of measurement

immunospectrometry

5

Description

leptin

Timepoint

The onset and end of the study

Method of measurement

ELISA

6

Description

Nutritional status

Timepoint

The onset and end of the study

Method of measurement

Measurement of energy and nutrients intake using 24-hour dietary recall method and anthropometric measurement using scale and stadiometer

7

Description

Total antioxidant capacity

Timepoint

The onset and end of the study
Method of measurement
Spectrophotometry

8

Description

LDL-C

Timepoint

The onset and end of the study

Method of measurement

Enzymatic colorimetric

9

Description

Total cholesterol

Timepoint

The onset and end of the study

Method of measurement

Enzymatic colorimetric

10

Description

Malondialdehyde

Timepoint

The onset and end of the study

Method of measurement

Spectrophotometry

11

Description

HDL-C

Timepoint

The onset and end of the study

Method of measurement

Enzymatic colorimetric

12

Description

Triglyceride

Timepoint

The onset and end of the study

Method of measurement

Enzymatic colorimetric

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: melatonin which is a natural hormone in the body and regulates sleep will be administered as oral supplement at a dose of 6 milligram (2 melatonin tablet, 3 mg each; made by Nature Made, USA) 2 hours before bed time for 40 days with weight

loss diet.

Category

Treatment - Drugs

2

Description

Control group will receive 6 mg placebo (2 tablet, 3 mg each containing cellulose, silicon dioxide and starch) 2 hours before bed time for 40 days with weight loss diet.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

The Clinics of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Reza Mahdavi

Street address

Faculty of Health and Nutrition, Tabriz University of Medical Sciences

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Tabriz University of Medical Sciences- Nutrition Research Center

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Faculty of Health and Nutrition, Tabriz University Of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor for Research, Tabriz University of Medical Sciences- Nutrition Research Center

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

Faculty of Health and Nutrition, Tabriz University Of
Medical Sciences

Full name of responsible person

Dr. Alireza Ostadrahimi

Position

Ph.D in Nutrition science

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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