

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Investigation of the effect of melatonin on the lipid levels in menopausal woman attending in selected Gynecology Clinics of Shiraz University of medical sciences, 1391

Protocol summary

Summary

The aim of this study was to investigate the effect of melatonin on lipid levels in healthy postmenopausal women. The study was designed as a randomized, double-blind, controlled clinical trial. 240 healthy postmenopausal women aged 60-40 referred to selected clinics enrolled to this study. In the intervention group (A), 120 women received melatonin tablets (3mg every night: 6-9 P.M) and, in the control group, 120 women received the placebo (Avicel) for 3 months. Key inclusion criteria were cessation of the menstrual cycle for at least 6 months and FSH above 40 IU. Exclusion criteria were a history of active liver, kidney, heart, thyroid, diabetes, and inflammatory diseases, hormone therapy for at least during last 6 months, and showing allergic reaction to the drug. Venous blood samples were taken from volunteers to determine the lipid status including values of LDL, HDL, TG and Cholesterol before intervention and three months after the intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090810774N1**

Registration date: **2016-05-08, 1395/02/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-08, 1395/02/19

Registrant information

Name

Nehleh Parandavar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5433 3686

Email address

parandavar@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-09-20, 1392/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of melatonin on the lipid levels in menopausal woman attending in selected Gynecology Clinics of Shiraz University of medical sciences, 1391

Public title

The effect of melatonin on the lipid levels

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria of the study: having general health based on the Goldberg's questionnaire (achieving score less than 23); married women between 40 to 60 years old; not using vitamin supplements; not having used hormone therapy during the last 3 months; complete physical health in physical examinations; cessation of the menstrual cycle for at least 6 months; and FSH above 40

IU. The exclusion criteria of the study: A history of active liver, kidney, heart, thyroid, diabetes and inflammatory diseases; inability to continue drug use for any reason; unwillingness to continue participation in the study; and showing allergic reaction to the drug. In addition, if any of the conditions listed in the inclusion criteria were violated at any time, the volunteer would be excluded from the study.

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **240**

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**

Medical Research Ethics Committee of Shiraz
University of Medical Sciences

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code**Approval date**

2012-12-23, 1391/10/03

Ethics committee reference number

6384-91

Health conditions studied**1****Description of health condition studied**

Menopause

ICD-10 code

N95.1

ICD-10 code description

Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

Primary outcomes**1****Description**

Serum lipid

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Lipid of plasma were measured based on the international units.

Secondary outcomes**1****Description**

Changes in body mass index

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Dividing weight in kilograms by the square of height in meters

Intervention groups**1****Description**

Intervention group: 3 milligram tablets of melatonin every night between 6 and 9 P.M. for 3 months

Category

Treatment - Drugs

2**Description**

Control group: 3 milligram tablets of placebo of melatonin every night between 6 and 9 P.M. for 3 month

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Motahhari Clinic

Full name of responsible person

Khadijeh Abdali

Street address

Namazi square, Motahhari Clinic, Obstetrics and gynecology ward

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellery of research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Gholam Reza Hattam

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellery of research, Shiraz University of Medical Sciences

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**

Shiraz University of Medical Sciences

Full name of responsible person

Khadijeh Abdali

Position

Master's degree in Midwifery

Other areas of specialty/work**Street address**

Namazi square, Fatemeh (PBUH) College of Nursing and Midwifery, Shiraz

City

Shiraz

Postal code**Phone**

+98 71 3647 4255

Fax**Email**

Abdalikh@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Fatemeh (PBUH) College of Nursing and Midwifery, Shiraz

Full name of responsible person

Khadijeh Abdali

Position

Master's degree in Midwifery, Faculty member

Other areas of specialty/work**Street address**

Namazi Sq. Fatemeh (PBUH) College of Nursing and Midwifery

City

Shiraz

Postal code**Phone**

+98 71 3647 4255

Fax**Email**

abdalikh@sums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Fatemeh (PBUH) College of Nursing and Midwifery, Shiraz

Full name of responsible person

Nehleh Parandavar

Position

Master's degree in Midwifery

Other areas of specialty/work**Street address**

Namazi Sq. Fatemeh (PBUH) College of Nursing and Midwifery

City

Shiraz

Postal code**Phone**

+98 71 3647 4255

Fax**Email**

parandavar@jums.ac.ir

Web page address

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