Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of the effect of melatonin on the climacteric symptoms and sexual disfunction in menopausal woman attending in selected Gynecology Clinics of Shiraz University of medical sciences, 1390

Protocol summary

Summary

The present clinical, randomized, double-blind, placebo-controlled trial aimed to determine the effect of melatonin on the climactrec symptoms and sexual dysfunction in menopausal women. The study population included the menopausal women from 40 to 60 years old attending the selected gynecology clinics of Shiraz University of Medical Sciences which had agreed to cooperate with the researchers. The study subjects were also required to have the following criteria: at least 12 months being passed from their last menstrual, FSH>40, a score of 28 or below in the female sexual function index, and Greene scale score of at least 21. In case the study subjects suffered from any illness, were not willing to continue participating in the study, and showed allergic reactions to medication, they were excluded from the study. After all, a total of 240 subjects were entered into the study and randomly divided into two groups of 120 receiving the drug and the placebo, respectively. At the beginning of the study, all the subjects' physical health was examined through physical examinations. Then, 3 milligram tablets of melatonin and the placebo of melatonin were given to the case and the control group, respectively for 3 months. Before and after the intervention, blood samples were taken from all the participants in order to investigate their FSH and estradiol. Moreover, the primary outcomes included climactrec symptoms as well as sexual function which were measured through questionnaires both before and during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201041548N13**

Registration date: **2012-08-01, 1391/05/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-01, 1391/05/11

Registrant information

Name

Khadijeh Abdali

Name of organization / entity

Fatemeh college of nursing and midwifery, Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Deputyof Shiraz University of medical sciense

Expected recruitment start date

2012-01-04, 1390/10/14

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of melatonin on the climacteric symptoms and sexual disfunction in menopausal woman

attending in selected Gynecology Clinics of Shiraz University of medical sciences, 1390

Public title
The effect of Melatonin on climactric symptoms and sexual disfunction
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: having general health according to the Goldberg's questionnaire; i.e., getting <23 score, Greene scale score of at least 21, being married and between 40 and 60 years old, not using vitamin supplements, not using soya, getting a score of 28 or below in female sexual function index, not having used hormone therapy during the last 3 months, not using anti-depression, tranquilizer, hypnotic, and antihypertensive drugs, being healthy after the physical examinations, amenorrhea for at least 6 months, and FSH>40. Exclusion criteria: Suffering from liver, kidney, and digestive diseases, inability to continue taking medication for any reason, unwillingness to cooperate after the beginning of the study, and showing allergic reactions to medication.
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
2011-12-10, 1390/09/19
Ethics committee reference number
ct-90-5880

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
Laboratory and clinical signs of menopause
Timepoint
Before intervention,1 ,2 and 3 month after intervention
Method of measurement
–In this study, climactric symptoms were measured through Greene questionnaire and female sexual function index questionnaire was used in order to assess the subjects' sexual function. In addition, FSH and EST were measured based on the international units.

Secondary outcomes

1

Description
Improvement of clinical symptoms
Timepoint
Before intervention,1,2 and 3 month after intervention
Method of measurement
Completed questionnaires before and during 3 months after clinical symptoms and laboratory measurements before and after intervention

Intervention groups

1

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

2

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

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Motahhari Clinic

Full name of responsible person

Street address
Namazi sq.

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Gholam Reza Hattam

Street address
Deputy for Research, seventh Floor, the central structure of Shiraz University of Medical Sciences, next to the Red Crescent, Zand Avenue

City
Shiraz

Grant name

Grant code / Reference number

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

Title of funding source
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
Fatemeh (PBUH) College of Nursing and Midwifery, Shiraz

Full name of responsible person
Khadijeh Abdali

Position
Master's degree in Midwifery, Faculty member

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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