

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Investigation of the effect of melatonin on the climacteric symptoms and sexual dysfunction 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 climacteric 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 climacteric 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

###### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

Research Deputy of Shiraz University of medical science

##### 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 dysfunction in menopausal woman

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

**Public title**

The effect of Melatonin on climactic 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, climactic 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

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

School of Medicine

**Full name of responsible person**

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Assistant Professor, Infertility Fellowship

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## Person responsible for updating data

### Contact

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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*