

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of melatonin and zolpidem compared with placebo on sleep disorders in premenopause and menopause women

Protocol summary

Summary

The plan consists of two parts. In the first part, Pre-menopausal and menopausal women diagnosed by gynecologist and filled the demographic questionnaire and Subjective Sleep Quality Inventory (PSQI) and if the total score is more than 5, they are selected as patients with sleep disorder. Then patients were randomly divided into three 30 person group which divided into case and control group. Randomly, for 6 weeks at night, one group treated with melatonin (3 mg), another group treated with Zolpidem (10 mg) and another group set as placebo group. Before trial and end of period (6 weeks) Subjective Sleep Quality Inventory (PSQI) will be filled for patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010216035N1**

Registration date: **2014-02-23, 1392/12/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-23, 1392/12/04

Registrant information

Name

somayeh shokrgozar

Name of organization / entity

guilan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1666 6628

Email address

dr_shokrgozar@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan university of medical science

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of melatonin and zolpidem compared with placebo on sleep disorders in premenopause and menopause women

Public title

Effects of melatonin and zolpidem compared with placebo on sleep disorders in premenopause and menopause women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of Pre- menopause and menopause to be confirmed; the absence of chronic medical conditions that can lead to sleep disorders. Exclusion criteria: Failure to diagnosis the menopause and premenopause; use of psychiatric drugs such as anti-psychotics and hypnotics and mood stabilizer drugs; chronic medical conditions leading to sleep disorders (diabetes, cardiovascular diseases, obesity); autoimmune Diseases; contraindication of taking melatonin (receiving medication of immunosuppressive drugs, sensitivity to melatonin, high blood pressure, liver dysfunction, history of seizures); sensitivity to Zolpidem;

receiving HRT (hormone replacement therapy); sleep disorder caused by taking certain psychiatric disorders (major depression , bipolar, anxiety, dementia); disasters and adverse event

Age

From **50 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Guilan university of medical sciences

Street address

Shafa educational and remedial center, 15 khordad street

City

Resht

Postal code

4193955599

Approval date

2013-12-07, 1392/09/16

Ethics committee reference number

1920341302

Health conditions studied

1

Description of health condition studied

Sleep disorder due to premenopause and menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Sleep Quality

Timepoint

6 weeks

Method of measurement

Subjective Sleep Quality Questionnaire(PSQI)

Secondary outcomes

1

Description

Quality of life

Timepoint

6 weeks

Method of measurement

SF-36 Quality of Life Questionnaire

Intervention groups

1

Description

Thirteen participants will be in 2 groups, including two tests and a control groups randomly during in 6 weeks at night, a group treated with melatonin (3 mg) and a group treated with Zolpidem (10 mg)

Category

Treatment - Drugs

2

Description

Thirteen participants in control group treated with placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital women's clinic

Full name of responsible person

Dr Somayeh Shokrgozar, Professor assistance Of psychiatry

Street address

Azzahra hospital, Namjoo street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan university of medical sciences

Full name of responsible person

Dr somayeh shokrgozar

Street address

Shafa educational and remedial center ,15 khordad avenue.

City

Rasht

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

Yes

Title of funding source

Guilan 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**

Guilan university of medical sciences

Full name of responsible person

Dr somayeh shokrgozar

Position

Psychiatrist

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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

