

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

A comparative study of escitalopram ,placebo and relaxation on hot flashes of patients with breast cancer

Protocol summary

Summary

This randomized double blind placebo controlled clinical trial will be conducted on 87 women with breast cancer, aged between 18-65 years , referring Kermanshah imam reza hospital and suffering from hot flash who volunteer for treatment. The patient will be randomly assigned in to 3 groups,2 intervention groups and one control group(n=29 each)In intervention groups patients, one group will take escitalopram 10 mg ,one time a day for 4 weeks and the other group will take relaxation methods ,once a day for 4 weeks. The control group will receive placebo tablet, one time a day for 4 weeks. The data collection will be done through interviews and a questionnaire considering demographic and hot flash diary. Then duration, severity and frequency of hot flashes will be assessed before treatment and 4 weeks after treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072834482N2**

Registration date: **2017-08-22, 1396/05/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-22, 1396/05/31

Registrant information

Name

Maryam Shirzadi

Name of organization / entity

Kermanshah University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 83 3826 5255

Email address

m_shirzadi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of escitalopram ,placebo and relaxation on hot flashes of patients with breast cancer

Public title

Effect of of escitalopram and relaxation on hot flashes of patients with breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having at least 4 hot flash attacks daily; Age range is 18 to 65 years; a history of breast cancer; not in acute phase of breast cancer, Ability to read and write and being able to answer questions ;Consent to participate in the study; Not concurrent using of any drugs that affect hot flash symptoms such as gabapentin, pregabalin, clonidine, SSRIs, herbal drugs and other treatments such as acupuncture, hypnotism ; no Non-malignant hypertension or CVA or MI or other uncontrolled organic problems and psychotic or bipolar

disorders Exclusion criteria: incidence of intolerable drug side effects, breast cancer relapse needing chemotherapy

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **87**

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Number 2 Building ,Shahid Beheshti Boulevard

City

Kermanshah

Postal code

Approval date

2017-02-05, 1395/11/17

Ethics committee reference number

KUMS.REC.1396.2

Health conditions studied

1

Description of health condition studied

Hot Flash

ICD-10 code

N95.3

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

hotflash frequency

Timepoint

before treatment and 4 weeks after treatment

Method of measurement

Hotflash diary

Secondary outcomes

1

Description

hotflash duration

Timepoint

before treatment and 4 weeks after treatment

Method of measurement

Hotflash diary

Intervention groups

1

Description

Intervention group: Escitalopram tab 10mg one time a day for 4 weeks

Category

Treatment - Drugs

2

Description

control group:Placebo tab one time a day for 4 weeks

Category

Placebo

3

Description

Intervention group: relaxation methods at least 30 minutes one time a day for 4 weeks

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Imam Reza Hospital

Full name of responsible person

Dr Maryam Shirzadi

Street address

Kermanshah Imam Reza Hospital

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Kermanshah University of Medical Sciences

Full name of responsible person

Dr Behrouz Hamzeh

Street address

Number 2 Building ,Shahid Beheshti Boulevard

City

Kermanshah

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, Kermanshah 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**

Kermanshah University Of Medical Science

Full name of responsible person

Dr Maryam Shirzadi

Position

Assistant Professor Of Psychiatry

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Position

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Full name of responsible person

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Position

Psychiatrist

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

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Fax**Email****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