

# 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

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

Imam Reza Hospital

**City**

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**Postal code****Phone**

+98 83 3427 6310

**Fax****Email**

m\_shirzadi@kums.ac.ir

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kermanshah University Of Medical Science

**Full name of responsible person**

Dr Maryam Shirzadi

**Position**

Psychiatrist

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### Person responsible for updating data

**Contact****Name of organization / entity**

Kermanshah University Of Medica Science

**Full name of responsible person**

Dr Maryam Shirzadi

**Position**

Psychiatrist

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

Imam Reza Hospital

**City**

Kermanshah

**Postal code****Phone**

+98 83 3427 6310

**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*