

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of the effect of Venlafaxine and Oxybutynin in controlling Hot Flashes in patients with Breast Cancer

Protocol summary

Study aim

A comparative study of the effect of Venlafaxine and Oxybutynin in controlling Hot Flash attacks in Patients with Breast cancer.

Design

Randomized Clinical trial with two groups of parallel intervention, double-blind, , phase 2, on 64 patients

Settings and conduct

In this study, Premenopausal patients with Breast cancer referred to Omid Hospital in Isfahan with complaints of Hot Flashes were randomly divided into two groups: receiving Venlafaxine 37.5 mg tablets daily or receiving 10 mg oxybutynin tablets daily for 8 weeks. They will be visited Before the intervention and the severity of the Hot Flashes will be assessed and recorded. Accordingly, feeling warmth without sweating (score 1), feeling warmth with sweating so that the patient is able to continue daily activities (score 2), feeling sever warmth with sweating so that the patient is not able to continue normal activities (score 3). Hot Flashes that wake the patient up(score 4). After eight weeks of medication, patients will be re-evaluated and the severity of the attacks will be re-evaluated and compared between the two groups. In this study, participating patients, principal researcher and statistical analyst will not know how participants are placed in intervention groups.

Participants/Inclusion and exclusion criteria

Pre-menopausal patients with Breast cancer complaining of Hot Flashes

Intervention groups

Intervention group 1: Patients in this group will receive one venlafaxine 37.5 mg tablet daily. Intervention group 2: Patients in this group will receive one 10 mg oxybutynin tablet daily.

Main outcome variables

Severity of Hot Flashes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210822052256N1**

Registration date: **2021-10-27, 1400/08/05**

Registration timing: **prospective**

Last update: **2021-10-27, 1400/08/05**

Update count: **0**

Registration date

2021-10-27, 1400/08/05

Registrant information

Name

Ali Akhavan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3235 0210

Email address

aliakhavan@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of Venlafaxine and Oxybutynin in controlling Hot Flashes in patients with Breast Cancer

Public title

Comparison of the effect of Venlafaxine and Oxybutynin in the Treatment of Hot Flashes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 years or older Pre-menopause At least 6 months have passed since the last Menstrual Period. Hot Flashes attacks Willingness to participate in the study

Exclusion criteria:

Uncontrolled Hypertension Chronic Heart Failure Chronic Kidney Disease Chronic Lung Failure Chronic Liver Failure Pregnancy Breast feeding Taking Anti Depressant Drugs Taking other Medications to control Hot Flashes over the past Two weeks

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients participating in the study will be divided into two groups getting Oxybutynin or Venlafaxine; using a Random Number Table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in this study will be divided into two groups receiving oxybutynin or venlafaxine, and patients in each group will receive one tablet per day, which will be in the same container and without the name and specifications of the Drug, without knowing the type of Drug.

Participants in the study, the Main Researcher, the Clinical Evaluator and the Statistical analyst of the study will not know how patients are placed in the groups receiving Venlafaxine or Oxybutynin.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine- Isfahan University of Medical Sciences

Street address

Hezar jarib Ave, Isfahan University of Medical Science

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Province

Isfahan

Postal code

8184917911

Approval date

2021-09-10, 1400/06/19

Ethics committee reference number

IR.MUI.MED.REC.1400.466

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Severity of Hot Flashes

Timepoint

At the beginning of the study and 8 weeks after taking Venlafaxine or Oxybutynin

Method of measurement

Check List

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Venlafaxine 37.5 mg tablets one tablet per day for 8 weeks Product of Lohman Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Intervention group: Oxybutynin 10 mg tablets, one tablet per day for 8 weeks, produced by Exir Pharmaceutical Company

Category

Treatment - Drugs

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Ali Akhavan

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Motahari Ave., Omid Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ali Akhavan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

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Fax**Email**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available