Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 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 warmness without sweating (score 1), feeling warmness with sweating so that the patient is able to continue daily activities (score 2), feeling sever warmness 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)

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+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 Sciense
City
Isfahan
Province
Isfehan
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 Loghman 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

Recruitment centers

1

Recruitment center

Name of recruitment center
Omid Hospital

Full name of responsible person
Ali Akhavan

Street address
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
Shaghayegh Haghjooy Javanmard

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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

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

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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Contact

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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