

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effect of escitalopram on pain, anxiety and depression in patients with breast cancer

Protocol summary

Study aim

This randomized clinical trial will be conducted to assess the effectiveness of escitalopram on pain, anxiety and depression of newly diagnosed breast cancer patients in Babol.

Design

In this clinical trial with control group, 40 newly diagnosed breast cancer patients with symptoms of depression and anxiety who do not have the exclusion criteria, will be allocated randomly in two groups of case and control.

Settings and conduct

In this study, 40 new breast cancer patients in the hospitals of Babol, who are referred to the study surgeon for mastectomy will be enrolled. Patients in the intervention group will be treated with escitalopram for 4 weeks and the control group will receive placebo during this period. The patients at the beginning of the study (before surgery) and 4 weeks after surgery will be evaluated for pain severity, depression and anxiety.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Newly diagnosed breast cancer patients who have anxiety and depression symptoms based on Hospital Anxiety and Depression Scale
Exclusion criteria: The history of high mood, suicidal thoughts, mental retardation, dementia and substance dependence

Intervention groups

Intervention group: 10 milligram per day escitalopram capsule manufactured in Abidi Pharmaceutical Company for four weeks
Control group: one placebo capsule containing starch for four weeks

Main outcome variables

Pain severity; Depressive symptoms; Anxiety symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150630022991N14**

Registration date: **2018-11-22, 1397/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-22, 1397/09/01**

Update count: **0**

Registration date

2018-11-22, 1397/09/01

Registrant information

Name

Sussan Moudi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 5683

Email address

sussan.mouodi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of escitalopram on pain, anxiety and depression in patients with breast cancer

Public title

Escitalopram in breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Newly diagnosed breast cancer patients With depression and anxiety symptoms

Exclusion criteria:

Previous history of high mood Suicidal thoughts Mental retardation Dementia Substance dependence

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The distribution of patients in the two treatment groups is conducted by block random allocation method. The free website of www.randomization.com is used to generate the allocation sequence. The resulting sequence is written in separate sheets and placed in sealed envelopes and is provided to the main investigator for the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients do not know about the type of drug or placebo which they receive.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafrooz avenue, Babol

City

Babol

Province

Mazandaran

Postal code

4136747176

Approval date

2018-10-06, 1397/07/14

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.152

Health conditions studied**1****Description of health condition studied**

Malignant neoplasm of breast

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Pain severity

Timepoint

At the beginning of the study and four weeks after intervention

Method of measurement

Visual Analogue Scale

2**Description**

Depressive symptoms

Timepoint

At the beginning of the study and four weeks after intervention

Method of measurement

Hospital Anxiety and Depression Scale

3**Description**

Anxiety symptoms

Timepoint

At the beginning of the study and four weeks after intervention

Method of measurement

Hospital Anxiety and Depression Scale

Secondary outcomes**1****Description**

Escitalopram- related side effects

Timepoint

In four weeks of intervention period

Method of measurement

Medical visit

Intervention groups

1

Description

Intervention group: 10 milligram per day escitalopram capsule manufactured in Abidi Pharmaceutical Company for four weeks

Category

Treatment - Drugs

2

Description

Control group: One placebo capsule containing starch for four weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Novin Nikbakhsh

Street address

Shahid Sargord Ghassemi avenue, Babol

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4716681451

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2

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Novin Nikbakhsh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi, MD, PhD

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rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi, MD

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Department of Psychiatry, Shahid Yahyanejad Hospital, Babol

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Web page address

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the data, such as information related to the primary and secondary outcomes, can be shared.

When the data will become available and for how long

The information related to the primary and secondary outcomes can be shared after publication of the final study report.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

In order to conduct similar studies in human populations, if a request email is received by the academic researchers, the requested information will be provided to them.

From where data/document is obtainable

Sussan Moudi, Psychiatrist, Associate Professor of Babol University of Medical Sciences

What processes are involved for a request to access data/document

The request email from the academic researchers should be sent to sussan.mouodi@gmail.com. Within 3 weeks after receipt of the email, the requested information will be sent by email.

Comments