Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Escitalopram efficacy on quality of life and prevention of depression in breast cancer patient with mastectomy

Protocol summary

Study aim
Escitalopram efficacy on quality of life and prevention of depression in breast cancer patients with mastectomy
Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment
Settings and conduct
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment in patients with mastectomy in Isfahan university of medical science heamatology and onchology hospitals
Participants/Inclusion and exclusion criteria
Women 18-65 y/o
Intervention groups
Escitalopram and placebo group
Main outcome variables
Depression score ; anxityscore ; quality of life score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180421039376N1**
Registration date: **2018-05-05, 1397/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-05, 1397/02/15**
Update count: **0**
Registration date
2018-05-05, 1397/02/15

Registrant information
Name
Zahra Zeinolabedini
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 4484 1289
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-26, 1397/02/06
Expected recruitment end date
2018-05-22, 1397/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Escitalopram efficacy on quality of life and prevention of depression in breast cancer patient with mastectomy

Public title
Escitalopram efficacy on quality of life and prevention of depression in breast cancer patient with mastectomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women 18-65 y/o Diagnosed with breast cancer stage I,II,IIIa and undergone modified radical mostectomy with or without chemothrapy and radiotherapy Consciously agreement Having at least literacy of writing and reading
Exclusion criteria:
Pregnancy and lactation History of conductive heart diseases Severe renal failure Moderate to severe hepatic failure History of SSRI drugs reactions and sensitivity Suffering from depression mood disorders, bipolar disorders or psychotic disorders based on DSM V criteria Any condition limiting life expectancy Any Use of anti

depression or anti anxiety drugs since 2 weeks before the study Any precipitation on group or individual psychotherapy sessions since 4 weeks before the study Suffering from any speech disorders Suffering from uncontrolled pain on the beginning of the study Having suicide plans or thoughts on the beginning of the study

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

Gender
Female

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Random number list

Blinding (investigator's opinion)
Double blinded

Blinding description
Double blind , the patients and the researcher

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Science

Street address
Hezarjirib

City
Isfahan

Province
Isfehan

Postal code
6581675653

Approval date
2017-02-08, 1395/11/20

Ethics committee reference number
Ir.mui.rec.1395.3.637

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
F06

ICD-10 code description
Other mental disorders due to known physiological condition

Primary outcomes

1

Description
Depression

Timepoint
0-4-8-12 week

Method of measurement
DASS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Escitalopram 10 mg tablets start once daily for the first 7 days, followed by increased dose 20 mg (two tablets) daily for the other 11 weeks. Depression and quality of life are measured respectively by DASS questionarrie and WHO questionarrie at the end of 4th, 8th, 12th week.

Category
Treatment - Drugs

2

Description
Control group: Placebo tablets similar to Escitalopram 10 mg tablets start once daily for the first 7 days ,followed by 2 tablets for the other 11 weeks. Depression and quality of life are measured respectively by DASS questionarrie and WHO questionarrie at the end of 4th, 8th, 12th week.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyedoshohada Hospital of Heamatology and onchology

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoy 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
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Zahra Zeinolabedini
Position
Student
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information

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