

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparing the efficacy of group-psychotherapy on breast cancer patients with major depressive disorder who are receiving citalopram

Protocol summary

Summary

This study is conducted to assess the efficacy of combined therapy (citalopram and group-psychotherapy) in breast cancer patients with depressive disorder. The main measures for patient enrollment are recently diagnosis of breast cancer besides psychiatrist's diagnosis on major depressive disorder. The patients with other major psychiatric disorders such as psychosis or substance abuse will be excluded. Other exclusive measures are neurologic diseases, mental retardation and endocrine disorders. Study population is female breast cancer patients who are referred to cancer-treatment centers affiliated to Babol University of Medical Sciences, in Northern Iran, near Caspian Sea. In this research, 40 patients in the two groups (case and control) will be examined. 20 patients in the control group will receive 20-40 milligram citalopram in a day; this dose will be adjusted based on the patient's tolerance and treatment response. 20 patients in the case group will participate in group cognitive-behavioral psychotherapy classes besides citalopram prescription. An educated psychologist will take this psychotherapy program. The two groups will be matched in their age. Group-psychotherapy sessions will be held weekly, free and at least 45 minutes in duration. The patients will be followed in the 3rd, 6th and 12th weeks of treatment. In these follows, the patients will be visited by the psychiatrist, their symptoms will be assessed and related questionnaires will be filled out. Treatment response is defined as a 50% reduction in depression and anxiety scores in comparison with the baseline scores. The primary outcomes which should be evaluated are treatment response and the patients' quality of life.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015063022991N1**

Registration date: **2016-01-23, 1394/11/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-23, 1394/11/03

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

Babol University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of group-psychotherapy on breast cancer patients with major depressive disorder who are receiving citalopram

Public title

Psychotherapy in Major Depressive Breast Cancer Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Breast cancer in the stage III or more; HADS score equals or more than 11 which can be due to symptomatic major depression; informed consent of the patient for participation in the study Exclusion criteria: severe psychiatric disorders such as psychosis or substance abuse; severe neurologic diseases; mental retardation; endocrine disorders

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Babol, Ganjafrouz ave.

City

Babol

Postal code

4136747176

Approval date

2014-06-09, 1393/03/19

Ethics committee reference number

4232

Health conditions studied

1

Description of health condition studied

Neoplasms

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

quality of life

Timepoint

3th, 6th and 12th weeks

Method of measurement

WHO Quality of Life Questionnaire (WHO-QOL BREF)

2

Description

severity of depression in the patient

Timepoint

3th, 6th and 12th weeks

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

Secondary outcomes

1

Description

the number of suicidal attempts

Timepoint

3th, 6th and 12th weeks

Method of measurement

self-report questionnaire

Intervention groups

1

Description

Control group: citalopram tablets, 20- 40 milligram per day (adjusted based on the patient tolerance and treatment response), for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Besides citalopram tablets (20-40 milligram per day) will participate in group cognitive behavioral psychotherapy classes. These group- therapy sessions are held weekly, free in price and lasting at least 45 minutes in each session. An educated psychologist will take this classes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

hospitals affiliated to Babol University of Medical Sciences

Full name of responsible person

Novin Nikbakhsh & Sussan Moudi

Street address

Babol, Shahid Beheshti & Shahid Yahyanejad Hospitals

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Ali Akbar Moghadamnia

Street address

Babol, Ganjafruz ave, Babol University of Medical Sciences

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Grant name

معاونت تحقیقات و فن آوری دانشگاه

Grant code / Reference number

2060

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

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

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi

Position

Faculty member

Other areas of specialty/work

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Person responsible for updating data

Contact

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