

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effectiveness of mirtazapine and citalopram on general health and quality of life in patients with major depression and breast cancer in the oncology ward

Protocol summary

Study aim

Comparison of the effectiveness of mirtazapine and citalopram on general health and quality of life in patients with major depression and breast cancer

Design

Sampling in this study will be easy and accessible. Samples will be randomly selected from patients with major depression based on the DSM-V criteria and breast cancer in stage 1-4 of the disease after surgery during chemotherapy and radiotherapy. Patients will be randomly assigned to two intervention groups of 21 patients treated with mirtazapine and citalopram.

Settings and conduct

Psychiatry, 5 Azar Hospital, Gorgan, clinical trial, drug therapy and assessment of general health and quality of life with relevant questionnaires, blinding by simple random method

Participants/Inclusion and exclusion criteria

1- People with breast cancer after radiotherapy surgery and undergoing chemotherapy or radiotherapy in stages 1 to 4 of disease progression 2- Age over 18 years and under 65 years 3- The level of education in middle school and higher 4- Existence of major depression criteria based on DSM-V criteria

Intervention groups

After the clinical interview, if there is a diagnosis of depression in the patient based on the DSM-V criteria, the patient enters the research project. After consultation with the hematology specialist, the patient will be randomly divided into one of the interventional categories of mirtazapine or citalopram. Patients in the mirtazapine group will receive 15 mg of mirtazapine daily, and patients in the citalopram group will receive 20 mg of citalopram daily. Patients in both groups will receive medication for 3 months and will be routinely asked about patient compliance during pre-scheduled visits and the results will be recorded in a pre-prepared

checklist.

Main outcome variables

Comparison of the effect of mirtazapine and citalopram on general health and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220406054440N1**

Registration date: **2022-05-10, 1401/02/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-10, 1401/02/20**

Update count: **0**

Registration date

2022-05-10, 1401/02/20

Registrant information

Name

Zohreh Keivanlou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3222 3392

Email address

dr.z.keyvanlou@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of mirtazapine and citalopram on general health and quality of life in patients with major depression and breast cancer in the oncology ward

Public title
Comparison of mirtazapine and citalopram in the treatment of depression in patients with breast cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Females with breast cancer after radiotherapy surgery and undergoing chemotherapy or radiotherapy in stages 1 to 4 of disease progression Age over 18 years and under 65 years Middle school education level and higher Existence of major depression criteria based on DSM-V criteria
Exclusion criteria:

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

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Divide into two groups with equal numbers by simple random method

Blinding (investigator's opinion)
Single blinded

Blinding description
Only treatment participants and Care providers are unaware of the allocation of study groups.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

5 Azar St., 5 Azar Hospital, Psychiatric Department

City

Gorgan

Province

Golestan

Postal code

4917763681

Approval date

2021-07-25, 1400/05/03

Ethics committee reference number

IR.GOUMS.REC.1400.104

Health conditions studied

1

Description of health condition studied

Major Depression, Breast Cancer, Mirtazapine, Citalopram

ICD-10 code

C50 , F32

ICD-10 code description

Malignant neoplasm of breast, major depression

Primary outcomes

1

Description

Quality of life, general health

Timepoint

One and three months after starting treatment

Method of measurement

Questionnaire GHQ-28 and SF-36

Secondary outcomes

empty

Intervention groups

1

Description

After the clinical interview, if there is a diagnosis of depression in the patient based on the DSM-V criteria, the patient enters the research project. After consultation with the hematology specialist, the patient will be randomly divided into one of the interventional categories of mirtazapine or citalopram. Patients in the mirtazapine group will receive 15 mg of mirtazapine daily, and patients in the citalopram group will receive 20 mg of citalopram daily. Patients in both groups will receive medication for 3 months and will be routinely asked about patient compliance during pre-scheduled

visits and the results will be recorded in a pre-prepared checklist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Oncology Department of Gorgan Martyrs Research and Training Center, Golestan University of Medical S

Full name of responsible person

Zohreh keyvanlou Shahrestanaki

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Email

Dr.z.keyvanlou@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Honarvar

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5 Azar Street

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Email

honarvar@goums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Zohreh Keyvanlou Shahrestanaki

Position

Psychiatric Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Questionnaire sf-36 and questionnaire GHQ-28

When the data will become available and for how long

starting in January 2023

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

No additional explanation.

From where data/document is obtainable

Dr.z.keyvanlou@gmail.com

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

Send request email and personal details

Comments