

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation of the effect of Mirtazapine on the quality of life of the breast cancer patients

Protocol summary

Study aim

Evaluation of the effect of Mirtazapine on improving the quality of life of the breast Cancer patients

Design

With the method of easy sampling of people referring to the chemotherapy and radiotherapy center who are eligible, after selecting the sample, they are randomly divided into two groups of intervention and control. Clinical trial with control group with parallel, double-blind and randomized groups is performed by permutation block method, phase 3 and on 110 patients.

Settings and conduct

Study place: Chemotherapy and radiotherapy center of Vasei hospital in Sabzevar; Type of blinding: single blind; How to blind: It is prescribed by the relevant therapist as a routine treatment for breast cancer

Participants/Inclusion and exclusion criteria

Inclusion criteria: Breast cancer; Not taking sleeping pills at the same time; Major depressive disorders according to DSM IV criteria Non-inclusion criteria: Concomitant cancer other than breast cancer; Taking other psychiatric medications before entering the study

Intervention groups

Intervention group (Mirtazapine): In this group, 55 patients are prescribed mirtazapine at a dose of 15-30 mg daily under the supervision of a psychiatrist based on the quality of life test score for 8 weeks. Control group: There are 55 patients in this group and no additional therapeutic intervention and action is prescribed except for routine cancer treatment.

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210425051075N1**

Registration date: **2021-10-15, 1400/07/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-15, 1400/07/23**

Update count: **0**

Registration date

2021-10-15, 1400/07/23

Registrant information

Name

Houman Kamranian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4465 1037

Email address

kamranianh@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-21, 1400/02/31

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Mirtazapine on the quality of life of the breast cancer patients

Public title

Effect of Mirtazapine on the quality of life of the breast cancer patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from cancer Major depressive disorder according to DSM IV criteria

Exclusion criteria:

Taking sleeping pills at the same time

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

By easy sampling method, people who refer to the Chemotherapy and Radiotherapy Center who are eligible are randomly divided into two groups of intervention and control after selecting the sample. In this study, individuals were divided into two groups using permutation block method. In this method, A represents the individual receiving the intervention and B represents the individual in the control group. Considering the quadruple block; We give AABB code 0, ABAB code 1, ABBA code 2, BAAB code 3, BBAA code 4 and BABA code 5. Then, using a table of random numbers, we randomly selected the starting point. Considering the order of the numbers in the table, we place the permutation corresponding to each number we encounter. Therefore, by selecting the numbers from the table, the method of assigning a total of 110 people to the two groups will be determined

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants in the blind plan had no knowledge of any other treatment other than routine cancer treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences; Shohadaye-Hasteiy blvd

City

Sabzevar

Province

Razavi Khorasan

Postal code

9414974877

Approval date

2021-03-08, 1399/12/18

Ethics committee reference number

IR.MEDSAB.REC.1399.192

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

c50

ICD-10 code description

Malignant neoplasm of breast

2

Description of health condition studied

Major depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Quality of Life

Timepoint

Study first and 8 weeks after starting mirtazapine

Method of measurement

WHO Quality of Life Questionnaire

2

Description

Anxiety

Timepoint

Study first and 8 weeks after starting mirtazapine

Method of measurement

WHO Quality of Life Questionnaire

3

Description

Sleep status

Timepoint

Study first and 8 weeks after starting mirtazapine

Method of measurement

WHO Quality of Life Questionnaire

4**Description**

Appetite status

Timepoint

Study first and 8 weeks after starting mirtazapine

Method of measurement

WHO Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients will be treated with Mirtazapine 15-30 mg daily for 8 weeks

Category

Treatment - Drugs

2**Description**

Control group: Continuation of routine therapeutic care and no additional therapeutic intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Chemotherapy and Radiotherapy Center in Vasei hospital

Full name of responsible person

Houman Kamranian

Street address

No.11, Motahhari 17 street

City

Sabzevar

Province

Razavi Khorasan

Postal code

9414974877

Phone

+98 51 4465 1037

Email

drkamranian@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences; Shohadaye-Hasteiy blvd

City

Sabzevar

Province

Razavi Khorasan

Postal code

9414974877

Phone

+98 51 4401 1000

Email

info@medsab.ac.ir

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Danial Kamrani

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No 48; Sayad-e-Shirazi blvd 21

City

Mashhad

Province

Razavi Khorasan

Postal code

9179986981

Phone

+98 51 3865 5892

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Houman Kamranian

Position

Assistante professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

No.17, Motahhari 11 street

City

Sabzevar

Province

Razavi Khorasan

Postal code

9414974877

Phone

+98 51 4465 1037

Email

drkamranian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Houman Kamranian

Position

Assistante professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

No.17, 11Motahhari st.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9414974877

Phone

+98 51 4465 1037

Fax**Email**

kamranianh@medsab.ac.ir

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

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

All data can be shared after making people unidentifiable

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Can be used by all researchers

Under which criteria data/document could be used

There are no restrictions for other researchers

From where data/document is obtainable

Daniel Kamrani Email danielkamrani96@gmail.com

Mobile 05138655892 Address: Sayad Shirazi St., No. 21

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

The applicant will send his / her application by email to the relevant researcher by mentioning the title of his / her research and the necessary information will be sent to him / her within a maximum period of 1 month.

Comments