

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of fluoxetine and placebo in improving the quality of life in patients with solid cancers referred to Imam Khomeini Hospital of Ardabil (double blind study)

Protocol summary

Summary

The study aims to compare the quality of life of the patients with solid cancer before and after treatment with fluoxetine and placebo. In this randomized, double-blind clinical trial, 150 patients with solid cancer referring to the hematology and oncology department of Imam Khomeini Hospital of Ardabil, Iran will enter the study. The main inclusion criteria include being over 15 years of age and lack of known psychological disorders. Exclusion criteria include lack of interest for participation, use of medications with depressive symptoms, being diagnosed with other psychiatric disorders. Patients will be given questionnaires containing personal information with two questions: 1) In the last month, have you had any feelings of disappointment or depression? 2) In the last month, have you had any feelings of lack of interest in doing your jobs? The answers will be ranked based on the scale of 0 to 4. Patients with scores of 5 or more will be entered into the next phase of the study. After the random selection of patients, Fluoxetine 20 mg and placebo will be prescribed orally to the intervention group and the control group, respectively, for 12 weeks. If side effects emerge, the medicine will be stopped and the patient will be excluded from the study. Before and after the intervention, the patients will answer a questionnaire of general health and quality of life. Based on the answers, the general health and quality of life status of the patients before and after the intervention will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012220751N1**

Registration date: **2015-02-18, 1393/11/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-18, 1393/11/29

Registrant information

Name

Behzad Mohammadi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3335 3905

Email address

behzad.mohammadi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

The Research Department of Ardabil University of Medical Sciences

Expected recruitment start date

2015-01-30, 1393/11/10

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of fluoxetine and placebo in improving the quality of life in patients with solid cancers referred to Imam Khomeini Hospital of Ardabil (double blind study)

Public title

The effect of fluoxetine in improving the quality of life in patients with cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: an age of 15 years or over; a definitive diagnosis of cancer confirmed by a specialist; laps of a minimum of one year from the diagnosis of the cancer; the lack of a known psychological problems ; being a patient with a definitive diagnosis of solid cancer being treated by or prepared for chemotherapy; being out of an acute phase of the disease and within stable clinical conditions; voluntary decision for participation. Exclusion criteria: lack of interest for participation in the study; use of medications with depressive symptoms; presence of other psychiatric diagnoses.

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical Sciences

Street address

Daneshgah Street, University of Medical Sciences,Ardabil,Iran

City

Ardabil

Postal code

Approval date

2013-11-30, 1392/09/09

Ethics committee reference number

Arums.REC.92.25

Health conditions studied

1

Description of health condition studied

cancer

ICD-10 code

c16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

improving the quality of life

Timepoint

befor and after intervention

Method of measurement

SF-36 questionnaire

2

Description

general health

Timepoint

before and after intervention

Method of measurement

general health questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group : oral prescription of similar placebo daily for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention group:oral prescription of fluoxetine capsules 20 mg daily for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology and Oncology Department of Ardabil
Emam Khomeini Hospital

Full name of responsible person

Behzad Mohammadi

Street address

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Shahram Habibzadeh

Street address

Daneshgah Street, University of Medical Sciences, Ardabil, Iran

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Behzad Mohammadi

Position

Resident of Internal Medicine

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Asgar Pirzadeh

Position

Hematology and Oncology Specialty

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Firouz Amani

Position

PHD of Biostatistics

Other areas of specialty/work

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Web page address

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