

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effectiveness of bupropion, fluoxetine, and methylphenidate in improving cancer-related fatigue

Protocol summary

Study aim

Comparison the efficacy of fluoxetine, bupropion and methylphenidate on the improvement of cancer related fatigue

Design

Three arm parallel-group double-blinded randomized clinical trial on 60 patients. Stratified Block Random Allocation is used for randomization.

Settings and conduct

This study will be done in clinics affiliated to Shahrekord University of Medical Sciences and Ayatollah Kashani hospital from September 2020 to September 2021. Patients with cancer-related fatigue will be referred by an oncologist. After obtaining informed consent, they will be randomly assigned to 3 groups: fluoxetine, bupropion, and methylphenidate. The patient will be evaluated using the Cancer Fatigue scale, Fatigue Visual Analogue scale, and Quality of life score in the European Organization for Research and treatment of cancer quality of life questionnaire and before the intervention, on weeks 4 and 8.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cancer patients suffering from fatigue; under chemotherapy; Patients who have not yet received an intervention (pharmacological or non-pharmacological) to treat cancer-related fatigue
Non-inclusion criteria: Leukemic patients; metastasis; Hb<10; respiratory or cardiac disease; balance problem; severe bone pain; past history of any major psychiatric disease

Intervention groups

Patients in the fluoxetine group will be prescribed fluoxetine 10 mg/d. During treatment, the dose increases to 40 mg per day, depending on the patient's tolerance. In the bupropion group, patients will receive 100 mg/d of bupropion. Depending on patients' tolerance it would be increased up to 300 mg/d. Patients in the methylphenidate group are given 10 mg of methylphenidate daily and can be increased to 30 mg per day depending on the patients' tolerance.

Main outcome variables

Fatigue score in Cancer Fatigue scale and Fatigue Visual Analogue scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180623040193N3**

Registration date: **2020-08-11, 1399/05/21**

Registration timing: **prospective**

Last update: **2020-08-11, 1399/05/21**

Update count: **0**

Registration date

2020-08-11, 1399/05/21

Registrant information

Name

Elham Zarean

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 38 3222 0016

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of bupropion, fluoxetine, and methylphenidate in improving cancer-related fatigue

Public title
Comparison of bupropion, fluoxetine, and methylphenidate in cancer-related fatigue

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Definite diagnosis of cancer from at least 2 month ago
Patients are undergoing outpatient chemotherapy
Lack of metastasis
Lack of any chronic cardiac or respiratory diseases or diabetes mellitus
Lack of severe bone pain and balance problem
Hemoglobin ≥ 10
Ability to read and write
Not receiving any type of treatment (drug or psychotherapy) for fatigue in the past
Not having leukemia
Lack of past history of any major psychiatric illnesses for which patient was hospitalized or medicated
Exclusion criteria:
Acute respiratory, cardiac or infectious diseases
Hemoglobin < 10
Uncontrolled hypothyroidism

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Given that the type of cancer may be a confounding factor, the samples are initially classified into three categories: breast cancer, gastrointestinal cancer, and other cancers. In each class, to assign samples to either the groups of fluoxetine, bupropion or methylphenidate, block randomization with a sample size of 6 is used. The sample assignment in each block is done using random allocation software.

Blinding (investigator's opinion)
Double blinded

Blinding description
To contemplate blindness, the researcher who allocated the patients had no role in the treatment and the investigating physician who was responsible for the treatment of the patients was not informed about the patients' medication. Further the patients were not aware of the nature of the allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
Kashani Ave, Shahrekord University of Medical Science
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Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
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8815713471

Approval date
2020-03-14, 1398/12/24

Ethics committee reference number
IR.SKUMS.REC.1398.240

Health conditions studied

1

Description of health condition studied
Cancer-related fatigue

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fatigue score in Cancer Fatigue scale and Fatigue Visual Analogue scale.

Timepoint
Before intervention, 1 month and 2 months after pharmacotherapy

Method of measurement
Cancer Fatigue scale, Fatigue Visual Analogue scale

Secondary outcomes

1

Description
The Quality of life score in European Organization for Research and treatment of cancer quality of life

questionnaire

Timepoint

Before intervention, 1 month and 2 months after pharmacotherapy

Method of measurement

European Organization for Research and treatment of cancer quality of life questionnaire version 3

Intervention groups

1

Description

Intervention group: Fluoxetine 20 mg/d (Exir pharmaceuticals, Iran) for the first 5 days then twice a day for the rest of the first month. In the second month, depending on the patient's tolerance, it could be increased to 40 mg/d.

Category

Treatment - Drugs

2

Description

Intervention group: Bupropion 100 mg/d (Exir pharmaceuticals, Iran) with identical shape and color as fluoxetine capsules for the first five days, then twice a day for the rest of the first month. In the second month depending on the patient's tolerance, it could be increased to 300 mg/d.

Category

Treatment - Drugs

3

Description

Intervention group: Methylphenidate 10 mg/d (Poursina pharmaceuticals, Iran) with identical shape and color as fluoxetine capsules for the first five days, then twice a day for the rest of the first month. In the second month depending on the patient's tolerance, it could be increased to 30 mg/d.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Mosharaf Niloufar

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Parastar Ave, Kashani Hosp

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shahre-kord 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Zarean

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Latest degree

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

Undecided - It is not yet known if there will be a plan to make this available

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