Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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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Chahar-Mahal-va-Bakhtiari

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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 pharmaceutics, 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 pharmaceutics, 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 pharmaceutics, 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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Sponsors / Funding sources

1

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Name of organization / entity

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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

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
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Position
Assistant professor
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Person responsible for updating data

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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