

# 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)

##### Phone

+98 38 3222 0016

##### Email address

e.zarean@skums.ac.ir

##### 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  $\geq 10$   
 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

##### City

Shahrekord

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

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

##### Street address

Parastar Ave, Kashani Hosp

##### City

Shahrekord

##### Province

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##### Postal code

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##### Phone

+98 38 3226 4825

##### Email

dr.ataee@ymail.com

### 2

#### Recruitment center

##### Name of recruitment center

Emam Ali Clinic

##### Full name of responsible person

Mosharaf Niloufar

##### Street address

Shariati Ave, Emam ali Clinic

##### City

Shahrekord

##### Province

Chahar-Mahal-va-Bakhtiari

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##### Phone

+98 38 3225 3743

##### Email

dr.ataee@ymail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Mehraban Sadeghi

##### Street address

Kashani Ave, Shahre

##### City

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##### Province

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##### Phone

+98 38 3334 2414

##### Email

pajoohesh@skums.ac.ir

##### 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

+98 38 3222 0016

**Email**

ezarean@gmail.com

**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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**Person responsible for updating data****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

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assistant professor

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Shahre-kord University of Medical Sciences

**Full name of responsible person**

Elham Zarean

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Postal code**

۸۸۱۶۸۵۴۶۳۳

**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