

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Randomized, placebo controlled, double blind clinical trial of the effect of bupropion on cancer-related fatigue

Protocol summary

Summary

Objective: Evaluation the effect of bupropion on cancer-related fatigue. Design: Randomized, double-blind, placebo controlled clinical trial. Setting: Patients with heterogenous type of cancer and diagnosed cancer-related fatigue in Seyed-Al-Shohada Clinic affiliated to Isfahan University of Medical Sciences. Major Inclusion and Exclusion criteria: Patients at least 18 years old, having a diagnosis of cancer with survival expectancy greater than 6 months, having a cancer-related fatigue defined by a score 4 or more on a brief fatigue inventory (BFI) screening scale and hemoglobin more than 9 g/dl taken less than 4 weeks before enrollment. Patients with Karnofsky Performance Scale of <50, history of convulsive seizure, current use (within 6 weeks preceding participation) of erythropoietin, psychostimulants or antidepressants, brain metastasis, history of fatigue prior to cancer diagnosis, any medical cause for fatigue identified on screening tests or a review of systems, hypersensitivity to bupropion and illiteracy will be excluded. Intervention: Eligible patients will be randomized to drug and placebo groups. Patients in drug group will be received bupropion sustained release (SR) 150 mg/day for 4 weeks. Main outcome measures: The primary outcome measure is the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) to evaluate efficacy of bupropion SR at improving fatigue symptoms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706191497N7**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Sarah Mousavi

Name of organization / entity

Clinical Pharmacy Department, Pharmacy Faculty,
Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 2567

Email address

smousavi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of
Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, placebo controlled, double blind clinical
trial of the effect of bupropion on cancer-related fatigue

Public title

Evaluation of bupropion effects on cancer related fatigue
in patients with cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were at least 18 years old, having a diagnosis of cancer with survival expectancy greater than 6 months, having a cancer-related fatigue defined by a score 4 or more on a brief fatigue inventory (BFI) screening scale that ranged from 0 (none) to 10 (as bad as it can be), and hemoglobin more than 9 g/dl taken less than 4 weeks before enrollment. The exclusion criteria were Karnofsky Performance Scale of <50, history of convulsive seizure, current use (within 6 weeks preceding participation) of erythropoietin, psycho stimulants or antidepressants, brain metastasis, history of fatigue prior to cancer diagnosis, any medical cause for fatigue identified on screening tests or a review of systems, hypersensitivity to bupropion and illiteracy.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave., Isfahan, IR Iran, 81746 73461

City

Isfahan

Postal code

81746 73461

Approval date

2014-10-31, 1393/08/09

Ethics committee reference number

3515/9/3

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C00-C97

ICD-10 code description

Malignant neoplasms

Primary outcomes

1

Description

Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)

Timepoint

Before intervention and after 4 weeks

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention and after 4 weeks

Method of measurement

Questionnaire

Intervention groups

1

Description

Patients in intervention group will be received bupropion sustained release (SR) (Abidi pharmaceutical, Tehran, Iran) 150 mg/day for 4 weeks.

Category

Treatment - Drugs

2

Description

Patients in control group will be received placebo of bupropion sustained release (SR) (Abidi pharmaceutical, Tehran, Iran) 150 mg/day for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed-Al-Shohada Hospital

Full name of responsible person

Sarah Mousavi

Street address

Hezar Jerib avenue, Isfahan University of Medical Sciences, Seyed-Al-Shohada Hospital

City

Isfahan

Fax**Email**

s.mousavi@pharm.mui.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr Sarah Mousavi

Position

PhD

Other areas of specialty/work**Street address**

Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code**Phone**

+98 31 3792 7072

Fax**Email**

s.mousavi@pharm.mui.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Nematbakhsh

Street address

Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Grant name

1347/9/12/پ

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Dr Sarah Mousavi

Position

Assistant professor

Other areas of specialty/work**Street address**

Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code**Phone**

+98 31 3792 7072

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

Isfahan University of Medical Sciences

Full name of responsible person

Dr Sarah Mousavi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Hezar Jerib avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code**Phone**

+98 31 3792 7072

Fax**Email**

s.mousavi@pharm.mui.ac.ir

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