

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy and safety of bupropion in cancer-related fatigue, a randomized double blind placebo controlled clinical trial

Protocol summary

Study aim

Treatment of fatigue in patients suffering from cancer more effectively

Design

Double blind placebo controlled clinical trial with a parallel group design of 30 patients, randomized based on the random number table, phase 3

Settings and conduct

The study will be done in Tuba Clinic of Mazandaran University of Medical Sciences. Patients will be divided into two 15-individual groups of intervention and control and the interventions will be performed on both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 and more; score of at least 4 based on BFI scale; fatigue with unknown reason for at least on week. Exclusion criteria: age under 18; history of use of CNS stimulants and antidepressants; history of suicide; history of seizure; pregnancy and lactation

Intervention groups

Bupropion will be administrated 75 mg/day (first three days) and 150 mg/day (rest of the days) to the patients for six weeks. Fatigue and depression will be evaluated based on corresponding criteria and scales. All approaches will be performed for control group but placebo will be used instead of Bupropion.

Main outcome variables

Degree of fatigue, depression and anxiety, quality of life, performance status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090613002027N12**

Registration date: **2018-06-01, 1397/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-01, 1397/03/11**

Update count: **0**

Registration date

2018-06-01, 1397/03/11

Registrant information

Name

Ebrahim Salehifar

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-14, 1397/01/25

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of bupropion in cancer-related fatigue, a randomized double blind placebo controlled clinical trial

Public title

Efficacy and safety of bupropion in cancer-related fatigue

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
 Patients suffering from cancer-related fatigue Score of at least 4 based on BFI (Brief Fatigue Inventory) scale (0-10) Fatigue with unknown reason for at least one week and more

Exclusion criteria:
 Age under 18 History of use of the CNS stimulants and antidepressants History of seizure History of use of erythropoietin in the last six weeks. History of suicide Use of MAOIs (Mono Amino Oxidase Inhibitors) in the last two weeks Liver and renal failure Pregnancy and lactation

Age
 From **18 years** old

Gender
 Both

Phase
 2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
 Target sample size: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Patients will enter the trial randomly based on the random number table.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 participants, principle investigator, healthcare providers, data collectors and outcome assessors

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences Ethical Committee

Street address

Mazandaran University of Medical Sciences, kilometer 18 of Farah Abad road, Sari, Iran

City

Sari

Province

Chahar-Mahal-va-Bakhtiari

Postal code

861-48175

Approval date

2017-09-20, 1396/06/29

Ethics committee reference number

IR.MAZUMS.REC.1396.3144

Health conditions studied

1

Description of health condition studied

Cancer related fatigue

ICD-10 code

Y43.3

ICD-10 code description

Drugs, medicaments and biological substances causing adverse effects in therapeutic use

Primary outcomes

1

Description

Fatigue score based on BFI scale

Timepoint

Before intervention and 2 and 6 weeks after intervention

Method of measurement

BFI questionnaire

2

Description

Fatigue score based on Functional Assessment of Chronic Illness Therapy (FACIT)

Timepoint

Before intervention and 2 and 6 weeks after intervention

Method of measurement

FACIT questionnaire

3

Description

Degree of depression and anxiety based on Hospital Anxiety and Depression scale (HADS)

Timepoint

Before intervention and 2 and 6 weeks after intervention

Method of measurement

HADS questionnaire

Secondary outcomes

1

Description

Performance status based on Eastern Cooperative Oncology Group (ECOG)

Timepoint

Before intervention and 2 and 6 weeks after intervention

Method of measurement

ECOG questionnaire

2

Description

Performance status based on Karnofsky Performance Status Scale

Timepoint

Before intervention and 2 and 6 weeks after intervention

Method of measurement

Karnofsky questionnaire

3

Description

Patient's quality of life based on European Organisation for Research and Treatment of Cancer QLQ-C30

Timepoint

Before intervention and 2 and 6 weeks after intervention

Method of measurement

EORTC QLQ-C30 questionnaire

Intervention groups

1

Description

Intervention group: administration of bupropion (made by Abidi pharmaceuticals) 75 mg once a day (for three days) then 75 mg twice a day till the end of study (six weeks)

Category

Treatment - Other

2

Description

Control group: administration of placebo once a day for the first three days then twice a day till the end of study

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tuba Clinic of Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Salehifar

Street address

Tuba Clinic, Khazar Square, Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

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Research Deputy, Mazandaran university of medical Sciences, Moallem Square, Sari, Iran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Mazandaran 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

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

Full name of responsible person

Ebrahim Salehifar

Position

Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Clinical Pharmacist

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available