

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

efficacy of Duloxetine for prevention of chemotherapy induced neuropathy in breast cancer patients

Protocol summary

Summary

the main goal of this study is to examine the efficacy of duloxetine in prevention of taxan- based chemotherapy induced neuropathy. 116 pateints, scheduled to undergo adjuvant paclitaxel therapy for breast cancer,will randomized to receive 30 mg duloxetine or plasebo in the first day of receiving paclitaxel till two weeks after finishing the last dose.in the first day and 6,12 and 24 weeks after that,patient will undergo neurologic examination and quality of life survey, based on NCI-CTCAE and fact-taxane questionnaire. at the end the data will analyzed and documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050227711N1**

Registration date: **2016-08-28, 1395/06/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

Azin Ahmari

Name of organization / entity

Shahid Beheshti University of Medical Siences

Country

Iran (Islamic Republic of)

Phone

+98 88059015

Email address

azin_ahmari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Breast Cancer Research Center of Jahad Daneshgahi
Tadbir Kalay-e Jam Pharmaceutical Company

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

efficacy of Duloxetine for prevention of chemotherapy induced neuropathy in breast cancer patients

Public title

efficacy of Duloxetine for prevention of chemotherapy induced neuropathy

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: -patient receiving paclitaxel -it is the first dose of paclitaxel -prior or ongoing treatment with other neurotoxic chemotherapeutic agents is not allowed - participants with out any documented medical history of nerve compression, leptomeningeal carcinomatosis, severe depression, suicidal idea, bipolar disease, alcohol abuse, glaucoma, diabetes, thyroid abnormality, markedly abnormal renal or liver function tests - not taking any medicine interfere in serotonin level -not taking any analgesic medicine routinely in two weeks before entering the trial exclusion criteria: -sever complications with duloxetine

Age

From **18 years** old to **80 years** old

Gender

Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **116**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple 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 Tehran University of Medical Sciences

Street address

Breast Cancer Research Center of Jihad Daneshgahi, number 146, South Gandhi street, Vanak square

City

Tehran

Postal code

15179-64311

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.ACECR.IBCRC.REC.1394.49

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

neuropathy

Timepoint

before starting intervention and 6-12-24 weeks after that

Method of measurement

NCI-CTCAE and FACT-TAXAN questionnaire

Secondary outcomes

1

Description

quality of life

Timepoint

before starting intervention and in 6-12-24 weeks after that

Method of measurement

FACT-TAXAN questionnaire

Intervention groups

1

Description

intervention group: duloxetine capsule (Duloxicap produced by Tadbir Kala-e Jam pharmaceutical company) taken orally 30 mg daily starting with first dose of Paclitaxel till 2 weeks after last course of Paclitaxel

Category

Treatment - Drugs

2

Description

control group: placebo of duloxetine PO daily starting with first dose of Paclitaxel till 2 weeks after last course of Paclitaxel

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Breast Cancer Clinic of Jihad Daneshgahi

Full name of responsible person

Dr Safa Najafi

Street address

Nazari street, Aboureihan street, Enghelab street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Breast Cancer Research Center of Jahad Daneshgahi

Full name of responsible person

Dr Olfatbakhsh

Street address

number 146, South Gandhi street, Vanak square

City

Tehran

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

Yes

Title of funding source

Breast Cancer Research Center of Jahad Daneshgahi

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Tadbir Kalay-e Jam Pharmaceutical Company

Full name of responsible person

Dr yousefi

Street address

number 1, Babak markazi alley, Africa street

City

Tehran

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

Yes

Title of funding source

Tadbir Kalay-e Jam Pharmaceutical Company

Proportion provided by this source**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

Shahid Beheshty University of Medical Sciences

Full name of responsible person

Dr Azin Ahmari

Position

resident of Radiation Oncology

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

Emam hossein hospital, Shahid madani street

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshty University of Medical Sciences

Full name of responsible person

Dr Ali Ghanbari Motlagh

Position

Radiation Oncologist

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

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshty University of Medical Sciences

Full name of responsible person

Dr Azin Ahmari

Position

resident of Radiation Oncology

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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