Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 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 Beheshty University of Medical Siences

Country

Iran (Islamic Republic of)

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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 chemotherapic 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 Siences
Street address
Breast Cancer Research Center of Jahad Daneshgahi, number 146, South Gandi 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 satrting 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 Paclitaxe
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 Paclitaxe
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 Jahad 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 Gandi 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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