Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect Of Doluxetine On The Treatment Of Neuropathy Induced By Paclitaxol In Breast Cancer Patients

Protocol summary

Study aim
the effect of doluxetine on the treatment of neuropathy induced by paclitaxol in breast cancer patients

Design
This is a double blind clinical trial study. The study population included all patients with breast cancer under treatment with Paclitaxel and have complain of neuropathy. A total of 40 individuals will be randomly assigned into two groups of intervention and control, for which the questionnaire will be completed. Both groups will test EMG-NCV. The intervention group will receive duloxetine capsule. The control group will receive the placebo. Then patients will be re-examined will be performed again.

Settings and conduct
This is a double blind clinical trial study. The study population included all patients with breast cancer and neuropathy under treatment Paclitaxel who attend to the hospital. A total of 40 individuals will be randomly assigned into two groups. Patients will be blind to their allocation into intervention and control groups.The physician investigator who offers the intervention and also a physician in physics will be blinded to groups allocation into intervention and control.

Participants/Inclusion and exclusion criteria
Persons over 18 years of age, Good co-operation, Patients with breast cancer under the first course of paclitaxel therapy, People under the age of 75

Intervention groups
The intervention group included 20 patients with breast cancer who were treated with paclitaxel. Patients were initially treated with duloxetine capsules. In the control group, patients will be treated with placebo containing starch similar in form and color of duloxetine.

Main outcome variables
Neuropathy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180805040700N1**
Registration date: **2018-12-06, 1397/09/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-06, 1397/09/15**
Update count: **0**

Registration date
2018-12-06, 1397/09/15

Registrant information

Name
Marziyeh Hesam

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3313 3145

Email address
m.hesam@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-02-19, 1397/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect Of Doluxetine On The Treatment Of Neuropathy Induced By Paclitaxol In Breast Cancer Patients

Public title
The Effect Of Doluxetine On The Treatment Of Neuropathy Induced By Paclitaxol In Breast Cancer Patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Persons over 18 years of age Good co-operation Patients with breast cancer under the first course of paclitaxel therapy People under the age of 75
Exclusion criteria:
intolerance of duloxetine
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
sample allocation into the control and intervention group will be done using a random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
Double-blind: 1.Patients will be blind to their allocation into intervention and control groups. 2. The physician investigator who offers the intervention and also a physician in physics who perform the assessment by EMG-NCV test for the patients will be blinded to groups allocation into intervention and control.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
amir al momenin Hospital
City
arak
Province
Markazi
Postal code
3848176941
Approval date
2018-01-21, 1396/11/01
Ethics committee reference number
IR.ARAKMU.REC.1396.270

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
first referral of patients and 12 weeks after start intervention
Method of measurement
Patient Neurotoxicity Questionnaire = PNQ, EMG-NCV of the four limbs Amplitude and latency analysis of mental and movement neurals of lower and lower fever

Secondary outcomes

empty

Intervention groups

1

Description
Control group: in the control group , patients treated with placebo, prepared by the pharmacist, will be examined in terms of their shape and color and the same size as doluxetine and containing Strachan.
Category
Placebo

2

Description
Intervention group: We treat patients by 30 milligram Doluxetine in first week and we treat 60 milligram in 11 week.
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Khansari Hospital

Full name of responsible person
Marzie Hesam

Street address
Ayatollah Khansari Teaching Hospital.Daneshgah street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Mohammad Arjomandzadegan

Position
Vice-Chancellor for Research of Arak University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Microbiology

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Person responsible for scientific inquiries

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Position
Resident

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Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
no
When the data will become available and for how long
no
To whom data/document is available
no
Under which criteria data/document could be used
no
From where data/document is obtainable
no
What processes are involved for a request to access data/document
no
Comments