

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Study aim

the effect of duloxetine 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)

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+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		Sciences
Public title		Street address
The Effect Of Doluxetine On The Treatment Of Neuropathy Induced By Paclitaxol In Breast Cancer Patients		amir al momenin Hospital
Purpose		City
Prevention		arak
Inclusion/Exclusion criteria		Province
Inclusion criteria:		Markazi
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		Postal code
Exclusion criteria:		3848176941
intolerance of duloxetine		Approval date
Age		2018-01-21, 1396/11/01
From 18 years old to 75 years old		Ethics committee reference number
Gender		IR.ARAKMU.REC.1396.270
Both		Health conditions studied
Phase		
3		
Groups that have been masked		
• Participant • Care provider • Investigator • Outcome assessor		
Sample size		1
Target sample size: 80		Description of health condition studied
Randomization (investigator's opinion)		breast cancer
Randomized		ICD-10 code
Randomization description		C50
sample allocation into the control and intervention group will be done using a random number table.		ICD-10 code description
Blinding (investigator's opinion)		Malignant neoplasm of breast
Double blinded		Primary outcomes
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		Description
Parallel		Neuropathy
Other design features		Timepoint
Secondary Ids		first referral of patients and 12 weeks after start intervention
empty		Method of measurement
Ethics committees		Patient Neurotoxicity Questionnaire = PNQ, EMG-NCV of the four limbs Amplitude and latency analysis of mental and movement neurals of lower and lower fever
1		Secondary outcomes
Ethics committee		
Name of ethics committee		
Ethics committee of Arak University of Medical		
		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

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Khansari Hospital

Full name of responsible person

Marzie Hesam

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

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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**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**Contact****Name of organization / entity**

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Position

Resident

Latest degree

Medical doctor

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Internal Medicine

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Person responsible for updating data**Contact**

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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