Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of duloxetine on paclitaxel- induced peripheral Neuropathy Among women with breast cancer.

Protocol summary

Study aim
Determination of the effect of duloxetine on paclitaxel-induced peripheral neuropathy in women with breast cancer

Design
"Crossover-Clinical trial" with Balaam's design, Double-blind, parallel and cross over groups of 60 patients. Randomization was centralized with random effect model in STATA.

Settings and conduct
This research will be performed in 1399 in the specialized oncology hospital of Seyed Al-Shohada in Isfahan and in a double-blind manner (patient and nurse).

Participants/Inclusion and exclusion criteria
Entry requirements: 1) Women with breast cancer Treated with paclitaxel 80 mg once a week 2)checked with Beck Depression Inventory (BDI-II)3 ؛)Life expectancy over 6 months No entry conditions: - Pregnant women or breastfeeding - women with diabetes or peripheral vascular disease, liver and kidney disease - Psychiatric diseases such as bipolar disorder, peripheral nerve disease such as carpal tunnel.

Intervention groups
there are four sequences in this study: Sequences A and B are cross ove: group A: patient will take 60 mg of dulextin for two weeks(daily), then they will receive a placebo for next two weeks, but in group B, they will have placebo for the first two weeks and then dolexin 60.(daily) Groups C and D are examined in parallel. third group will take only dolextin 60 daily for two weeks and the fourth group will have the placebo once a day for two weeks. for testing TNF-α, blood samples will be taken from the third and fourth groups before and after the end of the test.

Main outcome variables
because of increasing in paclitaxel induced peripheral neuropathy, we need a medicine for controling patient" pain.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201115049390N1**
Registration date: **2021-01-23, 1399/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-23, 1399/11/04**
Update count: **0**

Registration date
2021-01-23, 1399/11/04

Registrant information
Name
zahra rezaiyan
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5224 2618
Email address
n.rezaii22022@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-30, 1399/09/10
Expected recruitment end date
2021-03-20, 1399/12/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Effect of duloxetine on paclitaxel- induced peripheral Neuropathy Among women with breast cancer.

Public title
effect of dulexetine on paclitaxel- induced peripheral Neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1- Women with breast cancer (according to the pathological tests and graphies) Treat with paclitaxel 80 mg once a week checked with Beck Depression Inventory (BDI-II) . not treated any other chemotherapy drugs with Life expectancy over than 6 months
Exclusion criteria:
Pregnant or breastfeeding women Women with a history of diabetes or peripheral vascular disease Woman with a history of liver and kidney disease Woman with a history of Psychiatric diseases such as bipolar disorder woman a history of peripheral nerve disease such as carpal tunnel
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
patients will be randomly placed in one of four groups (n = 15). (To prevent data loss, 15 patients will be placed in each group and all groups will be matched with each other.) The type of study intended to eliminate the "Carryover" side effect of the previous drug was determined by the "Crossover-Clinical trial" designed by Balaam's design. The subjects will be determined based on the sample size formula and will be grouped into one of four sequences (A, B, C, D) in a simple random assignment.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs are prepared as original dulexetin and placebo. No information is given to the patient or nurse about the type of medication and only the researcher knew the type.
Placebo
Used
Assignment
Other
Other design features
The main feature of this study is that there are two groups: parallel and crassover

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of kashan University of Medical Sciences
Street address
5th of Qotb –e Ravandi Blvd, Kashan, IRAN
City
Kashan
Province
Isfehan
Postal code
87159-81151
Approval date
2020-10-28, 1399/08/07
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.133

Health conditions studied

1

Description of health condition studied
Paclitaxel induced peripheral neuropathy
ICD-10 code
G60-G64
ICD-10 code description
Polyneuropathy (diseases of several nerves) and other disorders of the peripheral nervous system

Primary outcomes

1

Description
Reducing peripheral neuropathy pain
Timepoint
Evaluation of neuropathic pain at the beginning and end of the intervention with measurement of TNF at the beginning and end of the intervention in two parallel groups.
Method of measurement
Using(The Brief Pain Inventory); (National Cancer Institute-Common Toxicity Criteria); von Frey or monofilament test; Visual analog scale; TNF alpha ELISA Kits

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with taxol-induced peripheral neuropathy who take dolextin 60 daily for two weeks. at the beginning and the end of the test, the patient's TNF alphaf will be measured .
Category
Treatment - Drugs

2

Description
Control group: Patients with taxol-induced peripheral neuropathy who are treated with placebo, will take it daily for two weeks and TNF-alpha measured at the beginning and end of the test.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyed Al-Shohada Hospital, Isfahan
Full name of responsible person
Mehran sharifi
Street address
Farshadi Alley, Khayam St., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
0000000000
Phone
+98 31 3236 8005
Email
Omid@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafsheh
Street address
Ravand Blvd, Vice-Chancellor for Research, Kashan University of Medical Sciences
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5554 2999
Email
Research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Zahra rezaiyan
Position
Masster student of medical physiology
Latest degree
Bachelor
Other areas of specialty/work
Physiology
Street address
Department of Physiology, Faculty of Medicine, University of Medical Sciences, Qutb Ravandi Blvd., Kashan, Iran
City
Isfahan
Province
Isfehan
Postal code
88141- 87159
Phone
+98 31 5554 0021
Email
N.rezaii2202@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work

Physiology

Street address
Department of Physiology, Faculty of Medicine, University of Medical Sciences, Qutb Ravandi Blvd., Kashan, Iran

City
Kashan

Province
Isfehan

Postal code
88141- 87159

Phone
+98 31 5554 0021

Email
Hamidi_gh@kaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Gholamali Hamidi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

Street address
Department of Physiology, Faculty of Medicine, University of Medical Sciences, Qutb Ravandi Blvd., Kashan, Iran

City
Kashan

Province
Isfehan

Postal code
88141- 87159

Phone
+98 31 5554 0021

Email
Hamidi_gh@kaums.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available