Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Feb 2026

comparison study of the effects of duloxetine and venlafaxine on neuropathy in breast cancer patients with taxol-induced acute peripheral neuropathy

Protocol summary

Study aim
Determination and comparison of the effect of two drugs duloxetine with venlafaxine on the symptoms of acute neuropathy caused by taxa in patients with breast cancer receiving taxane

Design
Clinical trial, with parallel groups, using the the random allocation rule of the restricted randomization method, phase 3 on 80 patients.

Settings and conduct
Imam Khomeini Hospital, Evaluation of symptoms based on a questionnaire

Participants/Inclusion and exclusion criteria
patients with breast cancer who treated with taxol (paclitaxel) for chemotherapy with peripheral neuropathic and neuropathic pain with confirmation of physical examination pain score 3 or more according to MacGill questionnaire No metastasis life expectancy more than 3 months Hospital anxiety and depression scale score less than 20 according to HADS questionnaire Neuropathic score more than 3 in DN4 questionnaire.

Intervention groups
patients in group 1 were given venlafaxine 37.5 mg. They use the medication once daily for one week. After one week if the patient tolerates the medication, the dose of the drug doubled to Venlafaxine 75mg for another 9 weeks. patients in group 2 were given duloxetine 30 mg. They use the medication once daily for one week. After one week if the patient tolerates the medication, the dose of the drug doubled to duloxetine 60 mg for another 9 weeks.

Main outcome variables
Scoring pain based on McGill pain questionnaire, scoring hospital anxiety and depression based on HADS questionnaire Scoring of neuropathy based on DN4 questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220115053723N1**
Registration date: **2023-01-01, 1401/10/11**
Registration timing: **retrospective**

Last update: **2023-01-01, 1401/10/11**
Update count: **0**

Registration date
2023-01-01, 1401/10/11

Registrant information

Name
Hanieh Radkhah

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2020-03-15, 1398/12/25

Actual recruitment start date
2019-02-20, 1397/12/01

Actual recruitment end date
2020-03-15, 1398/12/25

Trial completion date
2020-05-23, 1399/03/03

Scientific title
comparison study of the effects of duloxetine and venlafaxine on neuropathy in breast cancer patients with taxol-induced acute peripheral neuropathy

Public title
effects of duloxetine and venlafaxine on the taxol-induced neuropathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with breast cancer who treated with taxol (paclitaxel) for chemotherapy with peripheral neuropathic and neuropathic pain with confirmation of physical examination pain score 3 or more according to MacGill questionnaire No metastasis life expectancy more than 3 months Hospital anxiety and depression scale score less than 20 according to HADS questionnaire Neuropathic score more than 3 in DN4 questionnaire.

Exclusion criteria:
metastatic breast cancer pregnancy and breast feeding HADS score more than 20 using antidepressant and anti epileptic drugs and opioids paralytic neuropathic syndromes

Age
From **18 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the random allocation rule of the restricted randomization method has been used. The random allocation represents a large block for the entire sample size, and the number of individuals assigned to each group will be balanced at the end of the study. In this method, they selected the initial set of total sample sizes and then randomly interpreted them into different groups. In this study, patients were randomly divided into the two groups. Sortition was used to construct the sequence and the results were recorded.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Imam Khomeini Hospital -Tehran University of Medical Sciences

Street address
No. 23, Akbarian Azar st., Sattarkhan St., Tehran

City
Tehran

Province
Tehran

Postal code
1441654345

Approval date
2019-01-30, 1397/11/10

Ethics committee reference number
IR.TUMS.IKHC.REC.1397.327

Health conditions studied

1

Description of health condition studied
neuropathy

ICD-10 code
G64

ICD-10 code description
Other disorders of peripheral nervous system

Primary outcomes

1

Description
pain score 3 or more according to MacGill questionnaire

Timepoint
At the beginning of the study and 10 weeks after starting the drug

Method of measurement
MacGill questionnaire

2

Description
Hospital anxiety and depression scale score less than 20 according to HADS questionnaire

Timepoint
At the beginning of the study and 10 weeks after starting the drug

Method of measurement
HADS questionnaire

3

Description
Neuropathic score more than 3 in DN4 questionnaire

Timepoint
At the beginning of the study and 10 weeks after starting the drug

Method of measurement
DN4 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: duloxetine - Patients who met the criteria for entering the study were entered into the study after randomization, and these patients were entered after neurological examination and confirmation of neuropathy caused by taxanes with history and examination and questionnaire scores. In the duloxetine group, they were treated with 30 mg daily from the beginning. In case of tolerance and no side effects at the end of the first week, the drug dose reached 60 mg. At the end of the 10th week, the patients were examined by HADS, McGill and DN4 questionnaires, and QLQ questionnaire was also used to check the quality of life. In case of drug side effects and drug intolerance, the patient was excluded from the study.
Category
Treatment - Drugs

2

Description
Intervention group: venlafaxine - Patients who met the criteria for entering the study were entered into the study after randomization, and these patients were entered after neurological examination and confirmation of neuropathy caused by taxanes with history and examination and questionnaire scores. In the venlafaxine group, they were treated with 37.5 mg daily from the beginning. In case of tolerance and no side effects at the end of the first week, the drug dose reached 75mg. At the end of the 10th week, the patients were examined by HADS, McGill and DN4 questionnaires, and QLQ questionnaire was also used to check the quality of life. In case of drug side effects and drug intolerance, the patient was excluded from the study.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Hanieh Radkhah
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Imam Khomeini Hospital Complex, Dr. Gharib Street, Tehran
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Central Organization of Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Hanieh Radkhah
Position
Assistant professor
Latest degree
Specialist

Other areas of specialty/work
Internal Medicine
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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