

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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

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Province

Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

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Central Organization of Tehran University of Medical
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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

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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Position

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Latest degree

Specialist

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Position

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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