Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the efficacy and safety of the addition of lacosamide to duloxetine in the treatment of taxanes- induced peripheral neuropathy: a randomized double-blind placebo-controlled trial

Protocol summary

Study aim
Evaluation of the efficacy of lacosamide in the treatment of taxane-induced peripheral neuropathy

Design
This study is a randomized double-blind placebo-controlled clinical trial that will be performed on 60 patients.

Settings and conduct
All patients will receive duloxetine 30 mg daily for the first week and then 60 mg daily. Patients in the lacosamide group will receive a dose of 200 mg twice daily with the proposed titration. Also, patients in the placebo group will receive placebo with a similar dose. Numeric Pain Rating Scale, EORTC QLQ-C30 (version 3), CTCAE, and adverse effects will be recorded at baseline, end of week 6 and 12 of intervention. This study will be double-blind. In this way, the patient and the doctor will not know about the drug used (lacosamide or placebo). This study will be performed in Imam Khomeini Hospital in Sari.

Participants/Inclusion and exclusion criteria
People aged 18 years and older Patients with taxane-induced peripheral neuropathy Existence of moderate to severe neuropathic pain with PI-NRS score ≥4 Normal baseline ECG

Intervention groups
Patients will be included into two groups based on quadruple blocks: "lacosamide and duloxetine" and "placebo and duloxetine".

Main outcome variables
The severity of neuropathy based on CTCAE Pain rate based on Numeric pain rating scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090613002027N21**
Registration date: **2023-05-09, 1402/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-09, 1402/02/19**
Update count: **0**

Registration date
2023-05-09, 1402/02/19

Registrant information

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Ebrahim Salehifar

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-05, 1402/02/15

Expected recruitment end date
2024-03-05, 1402/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of the addition of

lacosamide to duloxetine in the treatment of taxanes-induced peripheral neuropathy: a randomized double-blind placebo-controlled trial

Public title
Evaluation of the efficacy and safety of lacosamide to duloxetine in the treatment of taxanes- induced peripheral neuropathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People aged 18 years and older Patients with taxane-induced peripheral neuropathy Existence of moderate to severe neuropathic pain with PI-NRS score ≥4 Normal baseline ECG

Exclusion criteria:
Patients with a history of neurological diseases such as hereditary or acquired neuropathies Patients with neuropathic pain due to conditions such as post-herpes neuralgia, uncontrolled diabetes with neuropathy, trigeminal neuralgia, spinal cord injury or other neurological diseases, known vitamin B12 deficiency, amyloidosis, neuromuscular diseases and connective tissue diseases Creatinine clearance less than 30 ml / min Severe liver failure History of allergy to lacosamide or duloxetine History of duloxetine or lacosamide use Evidence of severe systemic disease patients with epilepsy Drugs that interact with the study drugs including tricyclic antidepressants (TCAs), norepinephrine-specific serotonin reuptake inhibitors (SNRIs), and sodium channel blockers in the past three months Use of monoamine oxidase inhibitors (MAOIs) in the last fourteen days or simultaneously Drugs that interact with the study drugs including atazanavir, siponimod, carbamazepine, phenobarbital, phenytoin, amiodarone, sotalol, antiarrhythmic drugs that increase QT interval, including class IA and IC, beta-blockers and non-dihydropyridine calcium channel blockers, lidocaine, and mexiletine Pregnant or lactating women Dissatisfaction with participating in the study

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **3**
Patients will be evaluated and followed up at baseline, at the end of week 6 and at the end of week 12.

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be selected by continuous sampling and the patients will be placed in two control and test groups by Block Balanced Randomization (BBR) method. Using the free web system http://www.randomization.com/, the allocation sequence will be done. In this way, the number of subjects in each block is determined to be 4 and the letter A will be considered for the control group and the letter B will be considered for the test group, and the allocation sequence will be created for 60 samples in 15 blocks of 4 with the combination of letters A and B. became. In order to hide the allocation (Allocation Concealment) using the random number table, a random 4-digit number will be determined as the unique code of each patient so that the grouping status of the patient (A or B) remains hidden. The information about the blocks and the specific code of each patient will be available only for the head of the research.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be double-blind and the patient and the doctor will not know about the drug used (lacosamide or placebo).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar Square, Sari, Mazandaran Province

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Approval date
2022-04-12, 1401/01/23

Ethics committee reference number
IR.MAZUMS.REC.1401.067

Health conditions studied

1

Description of health condition studied
Taxane-induced neuropathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The severity of neuropathy based on CTCAE
Timepoint
Measurement of severity of neuropathy based on CTCAE at baseline and end of week 6 and end of week 12 of Lacosamide / placebo use
Method of measurement
Common Terminology Criteria for Adverse Events (CTCAE) version 5.0

2

Description
Pain rate based on Numeric pain rating scale
Timepoint
Measurement of pain rate based on Numeric pain rating scale at baseline and end of week 6 and end of week 12 of Lacosamide/placebo use
Method of measurement
Using Numeric pain rating scale

3

Description
The severity of neuropathy based on FACT/GOG-Ntx
Timepoint
Measurement of severity of neuropathy based on FACT/GOG-Ntx at baseline and end of week 6 and end of week 12 of Lacosamide / placebo use
Method of measurement
Using Functional Assessment of Cancer Therapy/Gynecologic Oncology Group – Neurotoxicity (FACT/GOG-Ntx)

4

Description
The severity of neuropathy based on Neuropathy pain scale
Timepoint
Measurement of severity of neuropathy based on Neuropathy pain scale at baseline and end of week 6 and end of week 12 of Lacosamide/placebo use
Method of measurement
Using Neuropathy pain scale

Secondary outcomes

1

Description
Quality of life based on EORTC QLQ-C30
Timepoint
Measurement of Quality of life-based on EORTC QLQ-C30 at baseline and end of week 6 and end of week 12 of Lacosamide/placebo use
Method of measurement
Using EORTC Quality of Life Study Group version 3

2

Description
Averse effects
Timepoint
Record adverse effects at any time during the study
Method of measurement
With monitoring the patient

Intervention groups

1

Description
Intervention group who suffers from taxane-induced neuropathy, the standard treatment is duloxetine 30 mg daily in the first week and then 60 mg daily with lacosamide drug of Abidi Pharmaceutical Company (UNIMIDE®) 100 mg tablet every 12 hours and from the second week if tolerated to 300 mg daily. From the third week to 400 mg daily (200 mg every 12 hours), continue until the end of the third month, and then reduce the weekly dose of 100 mg per day until discontinuation of the drug at the end of the fourth month. At the end of three months, duloxetine is first reduced to 30 mg daily for one week and then discontinued.
Category
Treatment - Drugs

2

Description
Control group who suffers from taxane-induced neuropathy: The standard treatment is duloxetine 30 mg daily for the first week and then 60 mg daily with placebo of lacosamide tablets (made in Abidi Pharmaceutical Company) every 12 hours for one week, from the second week 2 in the morning one night and from the third week two every 12 hours and continue until the end. The third month and then reduce the weekly dose of one placebo pill per day until the drug is stopped at the end of the fourth month. At the end of the third month, duloxetine is first reduced to 30 mg daily for one week and then discontinued.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Sari
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Ebrahim Salehifar
Position
professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no plan for publishing the protocol of the study because it is accessible in IRCT.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

All data are shareable after publishing

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Use in the practice and also future meta-analysis

From where data/document is obtainable

Ebrahim Salehifar Email: Esalehifar52@gmail.com

What processes are involved for a request to access data/document

Sending email to Dr Ebrahim Salehifar

Comments