

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A Comparative study of effectiveness of Venlafaxine and Duloxetine on peripheral neuropathy caused by chemotherapy

Protocol summary

Summary

This study will be done with Comparative investigation aim effectiveness of Venlafaxine and Duloxetine on peripheral neuropathy caused by chemotherapy. This study is a double-blind clinical trial. The study population will be included all patients with cancer and with peripheral neuropathy with neuropathic complaints referred to oncology clinic of Imam Reza Hospital in Kermanshah. A total of 156 persons will be selected and randomly assigned to experimental and control groups (two experimental groups, a control group). The questionnaire will be provided to the patients in all three groups. In the experimental group Venlafaxine and duloxetine will placed in coded containers with the lid closed and a container containing the drug will be delivered to the patient. The drug will be available within 1 month of consumption and how to use will be explained to the patient. The use of venlafaxine (37.5 mg capsules every 24 hours) and for duloxetine (capsules of 30 mg every 24 hours) is determined. The control group will receive placebo and one month after taking the drug, the questionnaire will be provided to the patients in all three groups and peripheral neuropathy will be checked beginning of the study, every two weeks and end of the study. Inclusion criteria were: No uncontrolled blood pressure, diabetes, addiction. Exclusion criteria: Patients treated with tamoxifen; Incidence of intolerable side effects; No on time and correct use of medicines; No patient cooperation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060922632N1**

Registration date: **2016-05-23, 1395/03/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-23, 1395/03/03

Registrant information

Name

Negin Farshchian

Name of organization / entity

Kermanshah University of Medicine

Country

Iran (Islamic Republic of)

Phone

+98 83 3823 2124

Email address

farshchian.n@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-05-14, 1395/02/25

Expected recruitment end date

2016-06-14, 1395/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative study of effectiveness of Venlafaxine and Duloxetine on peripheral neuropathy caused by chemotherapy

Public title

effectiveness of Venlafaxine and Duloxetine on peripheral neuropathy caused by chemotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were: Patients with cancer and with peripheral neuropathy caused by chemotherapy; Patient written consent; No uncontrolled blood pressure, diabetes, addiction. Exclusion criteria: Patients treated with tamoxifen; Incidence of intolerable side effects; No on time and correct use of medicines; No patient cooperation

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **156**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2015-11-23, 1394/09/02

Ethics committee reference number

kums.rec.1394.433

Health conditions studied

1

Description of health condition studied

pripheral neuropathy

ICD-10 code

G62.0

ICD-10 code description

Drug-induced polyneuropathy

Primary outcomes

1

Description

Severity of neuropathy

Timepoint

The first, second week and end of the study (fourth week)

Method of measurement

Based on the visual analogue scale (VAS), Sheehan Disability Scale, Brief Pain Inventory, Depression Inventory (Mood), Beck Depression Inventory (BDI-11), Clinical Global Impression Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1 will receive Venlafaxine capsules 37.5 mg every 24 hours for a month

Category

Treatment - Drugs

2

Description

Control group will receive placebo every24 hours for a month

Category

Placebo

3

Description

Intervention group 2 will receive duloxetine capsules 30 mg every 24 hours for a month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Avisa Alavi

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Avisa Alavi

Position

Medical student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Avisa Alavi

Position

Medical Student

Other areas of specialty/work

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Fax

Email

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty