Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the therapeutic effects of oral duloxetine alone and with combination gel on reduction of symptoms of chemotherapy-induced peripheral neuropathy

Protocol summary

Study aim
The aim of this study is to compare the therapeutic effects of oral duloxetine alone and with a combination gel (containing baclofen, amitriptyline, and ketamine) to reduce Chemotherapy-induced peripheral neuropathy symptoms.

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
The present study will be done on 90 patients referring to Shahrekord Ayatollah Kashani hospital under treatment with neurotoxic chemotherapy drugs, who developed peripheral neuropathy symptoms.They were selected by convenience sampling.

Participants/Inclusion and exclusion criteria
Inclusion criteria were being patients under treatment with neurotoxic chemotherapy drugs, Which have symptoms of peripheral neuropathy and have normal blood calcium and magnesium levels; Patients with diabetes or other causes of peripheral neuropathy also patients with History of severe hypersensitivity to duloxetine will not enrolled in the study.

Intervention groups
Patients will divide into three groups of 30 each. Group A will receive oral duloxetine 30 mg once daily along with topical placebo gel 1.3 g twice a day. Group B will receive oral duloxetine 30 mg once daily along with topical combination gel (10 mg of baclofen, 40 mg of amitriptyline, and 20 mg of ketamine) twice daily. 1.3 g. The placebo gel contained a gel base without pharmaceutical compounds. The combination gel will be applied to areas of pain, numbness, or paresthesia and will not be applied to more than 4 areas in each turn of application. Group C will receive a placebo gel twice a day 1.3 g (one table spoon). Before and 4 weeks after intervention, all patients will be examined by a questionnaire, for 20 symptoms of peripheral neuropathy which was derived from the the international instrument QLQ-CIPN20,

Main outcome variables
Changes in the symptoms of neuropathy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110514006480N16**
Registration date: **2018-08-01, 1397/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-01, 1397/05/10**
Update count: **0**

Registration date
2018-08-01, 1397/05/10

Registrant information

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Name of organization / entity
Shahrekord University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-01, 1397/05/10

Expected recruitment end date

2018-11-01, 1397/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effects of oral duloxetine alone and with combination gel on reduction of symptoms of chemotherapy-induced peripheral neuropathy

Public title

Effects of oral duloxetine on reduction of symptoms of peripheral neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients under treatment with neurotoxic chemotherapy drugs, Which have symptoms of peripheral neuropathy Normal blood calcium and magnesium levels

Exclusion criteria:

Having diabetes and other causes of peripheral neuropathy History of severe hypersensitivity to duloxetine

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into three groups by simple random sampling and Using three categories of cards that listed on them the letters A, B and C.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study considering the use of similar drug forms in all three groups participants, researcher, as well as the assessor, are not aware of the type of drug used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Deputy of Research and Technology, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2017-02-01, 1395/11/13

Ethics committee reference number

IR.SKUMS.REC.1395.290

Health conditions studied

1

Description of health condition studied

Chemotherapy-induced peripheral neuropathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean scores of peripheral neuropathy symptoms in LQ-CIPN20 questionnaire

Timepoint

Before the intervention, 4 week after treatment with duloxetine

Method of measurement

LQ-CIPN20 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients will receive oral duloxetine 30 mg once daily (in the morning) along with topical placebo gel 1.3 g twice (morning and night) a day

Category

Treatment - Drugs

2

Description
Intervention group 2: Patients will receive oral duloxetine 30 mg once daily (morning) along with topical combination gel (10 mg of baclofen, 40 mg of amitriptyline, and 20 mg of ketamine) twice daily (morning and night) 1.3 g.
Category
Treatment - Drugs

3

Description
Control group: Patients will receive placebo gel twice a day (morning and night) 1.3 g.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord ayatollah Kashani hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Roholla Masoumi
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Oncologist
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Person responsible for updating data

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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