

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

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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

Dr Rohollah Masoumi

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Ayatollah Kashani hospital, Parastar Ave, Shahrekord

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Seyed Kamal Solati

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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

Position

Oncologist

Latest degree

Specialist

Other areas of specialty/work

Oncology

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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