Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of Duloxetine effect on Oxaliplatin induced peripheral neuropathy prophylaxis

Protocol summary

Study aim
Evaluation of the effect of duloxetine on the prevention of neuropathy induced by oxaliplatin

Design
parallel randomized clinical trial consist of placebo and experimental group

Settings and conduct
We enrolled 40 patients who candidate to receive their first course of chemotherapy based on oxaliplatin regimen on Taleghani hospital. They were treated with duloxetine by increasing the dose from 30 mg/day for first week to 60 mg BD untill 12weeks. Patients' pain intensity was rated at every course and their quality of life was rated at baseline and 12 weeks after duloxetine administration.

Participants/Inclusion and exclusion criteria
patients > 18 years old who candidate for their first course of chemotherapy based on oxaliplatin regimen, are included to the study. / patients who have uncontrolled diabetes or hypertension, metastatic stage or using drugs which have significant interaction with duloxetine are not allowed to enter the study.

Intervention groups
Experimental and control group consist of over 18 years old patient who candidate to receive their first course of chemotherapy based on oxaliplatin regimen on Taleghani hospital. In the patient group, on the first day of the onset of the Oxal platinum chemotherapy regimen, take a 30 mg capsule of duloxetine in the morning, after one week, receive a capsule in the morning and one midday capsule. In the placebo group, patients received the same capsule of the placebo produced by the same drug company at the first week and from the second week for the first 12 weeks, according to the same method of the test group.

Main outcome variables
neuropathy (NCI-CTCAE and FACT/GOG-NTX-13 version 14) quality of life and their emotional state (FACT-C version 4)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100127003210N15**
Registration date: **2018-06-25, 1397/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-25, 1397/04/04**
Update count: **0**

Registration date
2018-06-25, 1397/04/04

Registrant information

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Maria Tavakoli Ardakani

Name of organization / entity
Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-02-19, 1395/12/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Duloxetine effect on Oxaliplatin induced peripheral neuropathy prophylaxis

Public title
Evaluation of Duloxetine effect on Oxaliplatin induced peripheral neuropathy prophylaxis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Over 18 years old The candidate patient is going to get his/her first chemotherapy course with Oxaliplatin drug

Exclusion criteria:
The patient has no uncontrolled diabetes mellitus or uncontrolled hypertension The patient is not taking drugs which have interaction with Duloxetin The patient is not on liver metastatic stage History of duloxetine allergy hepatic impairment clcr < 30ml/min and ESRD

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In covariate adaptive randomization, a new participant is sequentially assigned to a particular treatment group by taking into account the specific covariates and previous assignments of participants. in this study covariants factors include : 1.sex 2.age 3.cancer stage. we used Graphpad prism for randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Vali-e-asr ave., Niyayesh junction

City
Tehran

Province
Tehran

Postal code
1991953381

Approval date
2016-06-14, 1395/03/25

Ethics committee reference number
IR.SBMU.PHNM.1395.418

Health conditions studied

1

Description of health condition studied
colorectal cancer

ICD-10 code
C18

ICD-10 code description
malignant neoplasm of colon

Primary outcomes

1

Description
peripheral neuropathy

Timepoint
every 2-3 week

Method of measurement
FACT/GOG-NTX-13 and NCI-CTCAE questionaire

Secondary outcomes

1

Description
quality of life

Timepoint
at baseline and 12 weeks later

Method of measurement
FACT-C version 4 questionaire

Intervention groups

1

Description
Intervention group: patient who take duloxetine 30mg/d for first week and then 30 mg BD to 12 weeks

Category
Treatment - Drugs

2

Description
Control group: Patients in this group receive one placebo capsule during the first week and then take 2 placebo capsules until 12th week of study.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani hospital

Full name of responsible person
Rokhsareh soufi

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Arabi St., Yaman St., Chamran highway.,Velenjak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Rokhsareh Soufi

Position
Pharm D student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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A Level or less

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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

Information are confidential

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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