Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Efficacy of Duloxetine for the prevention of Oxaliplatin Induced Peripheral Nephropathy (OIPN)- A double blinded placebo controlled phase 2 study

Protocol summary

Study aim
The aim of this study was to evaluate the efficacy and safety of duloxetine for prevention of oxaliplatin induced peripheral neuropathy.

Design
Randomized double-blinded, Placebo-controlled phase 2 clinical trial. 23 patients should be enrolled in each group.

Settings and conduct
Radiation Oncology Research Center, Cancer Institute, Imam Khomeini Hospital Complex.

Participants/Inclusion and exclusion criteria
The eligible patients were aged 18-75 with good performance status (ECOG<2) who had pathologically confirmed cancer and were candidate for receiving oxaliplatin (XELOX or FOLFOX) in the course of their cytotoxic treatment.

Intervention groups
Duloxetine capsule was given 60 mg orally from the first day of chemotherapy to day 14 of each chemotherapy cycle. The first dose was given 1 hour before the first course of chemotherapy. The placebo group received placebo the same way as duloxetine group.

Main outcome variables
Oxaliplatin Induced Peripheral Neuropathy (OIPN)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170211032494N2**
Registration date: **2019-01-04, 1397/10/14**
Registration timing: **retrospective**

Last update: **2019-01-04, 1397/10/14**
Update count: **0**

Registration date
2019-01-04, 1397/10/14

Registrant information

Name
Nima Mousavi Darzikolaee

Name of organization / entity
Radiation Oncology Research Center, Cancer Institute, Tehran 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
2016-07-22, 1395/05/01

Expected recruitment end date
2018-02-19, 1396/11/30

Actual recruitment start date
2016-07-22, 1395/05/01

Actual recruitment end date
2018-02-19, 1396/11/30

Trial completion date
2018-02-19, 1396/11/30

Scientific title
Efficacy of Duloxetine for the prevention of Oxaliplatin Induced Peripheral Nephropathy (OIPN)- A double blinded placebo controlled phase 2 study

Public title
Prevention of Oxaliplatin Induced Peripheral Neuropathy (OIPN)

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients have pathologically confirmed cancer; Aged 18-75; Candidate for receiving at least 4 courses of Oxaliplatin; Good performance status (based on ECOG)

Exclusion criteria:

History of diabetes mellitus; Previous neuropathy; Chronic renal or liver disease; Consumption of neurotoxic/neurotropic/neuroleptic drugs

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Actual sample size reached: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible patients were randomized into two groups using randomly assigned permuted blocks method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were known as group C or D. Neither staff responsible for gathering the data nor the patients were aware of the drug (placebo or Duloxetine) which was given to them by the researcher.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Radiation Oncology Research Center, Cancer Institute , Imam Khomeini Hospital Complex

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2016-04-26, 1395/02/07

Ethics committee reference number

IR.TUMS.REC.1395.2474

Health conditions studied

1

Description of health condition studied

Oxaliplatin Induced Peripheral Neuropathy (OIPN)

ICD-10 code

Y43.3

ICD-10 code description

Other anti neoplastic drugs

Primary outcomes

1

Description

Oxaliplatin Induced Peripheral Neuropathy (OIPN)

Timepoint

Before, During and after each chemotherapy cycle, 6 weeks after last chemotherapy cycle.

Method of measurement

Subjective evaluation by Common Terminology Criteria for Adverse Effect, Objective assessment by Nerve Conducting Study.

Secondary outcomes

1

Description

Safety profile of Duloxetine

Timepoint

Before, During and after each chemotherapy cycle, 6 weeks after last chemotherapy cycle.

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Duloxetine capsule (Duloxicap produced by Tadbir Kala-e Jam pharmaceutical company) was given 60 mg once a day orally from the first day to the day 14 of each cycle (7 days rest in 3 week courses). Patients were given at least 4 cycle of Oxaliplatin containing chemotherapy. The first capsule was given 1 hour before the chemotherapy administration.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule with the same appearance as Duloxetine capsule (produced by Tadbir

Kala-e Jam pharmaceutical company) was given once a day orally from the first day to day 14 of each cycle (with 7 days rest in 3 week courses). The first capsule was given 1 hour before the chemotherapy.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Radiation Oncology Research Center, Cancer Institute, Imam Khomeini Hospital Complex

Full name of responsible person
Nima Mousavi Darzikolaee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ali Sahraeeian

Street address
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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
Tehran University of Medical Sciences

Proportion provided by this source
1

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Radiation Oncology Research Center, Cancer Institute , Imam Khomeini Hospital Complex

Full name of responsible person
Nima Nousavi Darzikolaee

Position
Radiation Oncologist

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

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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
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