Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of Gabapentin for the Prevention of Paclitaxel Induced Peripheral Neuropathy

Protocol summary

Summary

Chemotherapy induced neuropathy is a dose limiting and disturbing side effect of taxane which impacts the quality of life in cancer survivors. Purpose of this sudy is to to assess the efficacy of concurrent gabapentin with paclitaxel based chemotherapy in preventing chemotherapy induced neuropathy in breast cancer patients This randomized controlled double-blinded clinical trial wiil be done in 2010-2011 in Cancer institute, Tehran, Iran. Forty women aged 18-65 with pathologically confirmed non-metastatic breast cancer after completion of four cycles of doxorubicin and cyclophosphamide will be enrolled. The subjects randomized into two groups of paclitaxel chemotherapy with gabapentin 300mg/three times a day oral or placebo for two weeks started at day 1 of each cycle. Nerve conduction studies would be done before the first and 6 weeks after the last cycle of paclitaxel. Between the cycles the patients would be visited and questioned of the symptoms of neuropathy graded based on CTCAE4. Two groups will be compared based on the relative frequency of neuropathy and NCV studies.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021132494N1**
Registration date: **2017-04-30, 1396/02/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-30, 1396/02/10

Registrant information

Name

Nima Mousavi Darzikolaee

Name of organization / entity

Radiation Oncology Research Center, Cancer Institute, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 0945

Email address

mousavi-n@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Bakhtar Bioshimi Company

Expected recruitment start date

2010-07-31, 1389/05/09

Expected recruitment end date

2011-07-31, 1390/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Gabapentin for the Prevention of Paclitaxel Induced Peripheral Neuropathy

Public title

Prevention of Chemotherapy Induced Neuropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : Women who have pathologically confirmed non metatstatic breast cancer; aged 18-65; candidate for receiving 4 course of paclitaxel ; good performance status (based on Karnofsky Score) 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 **65 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran

City

Tehran

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

93-02-30-25786

Health conditions studied

1

Description of health condition studied

chemotherapy induced neuropathy

ICD-10 code

y43.3

ICD-10 code description

Other antineoplastic drugs

Primary outcomes

1

Description

taxane induced neuropathy

Timepoint

befor and after each chemotherapy session

Method of measurement

taking history and physical exam

Secondary outcomes

1

Description

objective neuropathy

Timepoint

befor begining chemotherapy session and 6 week after last chemotherapy session

Method of measurement

nerve conducting study

Intervention groups

1

Description

in intervention group Gabapentin is prescribed 300mg orally for the first day, 300mg every 12 hour for the second day and 300mg every 8 hour for the third to fourteenth day of each chemotherapy cycle.

Category

Treatment - Drugs

2

Description

in control group placebo is prescribed orally one capsule for the first day, one capsule every 12 hour for the second day, one capsule every 8 hour for the third to fourteens day of 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

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bakhtar Bioshimi Company
Full name of responsible person
Reza Malekzadeh
Street address
Kermanshah Industrial Town, Kermanshah
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bakhtar Bioshimi Company
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
Radiation Oncology Research Center, Cancer Institute , Imam Khomeini Hospital Complex
Full name of responsible person
Nima Mousavi Darzikolaee
Position
Resident of Radiation Oncology
Other areas of specialty/work
Street address
Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran
City
Tehran
Postal code
1419733141
Phone
+98 21 6694 8679
Fax
Email
mousavi-n@razi.tums.ac.ir
Web page address

Person responsible for scientific 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
Resident of Radiation Onclology
Other areas of specialty/work
Street address
Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran
City
Tehran
Postal code
1419733141
Phone
+98 21 6694 8679
Fax
+98 21 6658 1633
Email
mousavi-n@razi.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Radiation Oncology Research Center, Cancer Institute , Imam Khomeini Hospital Complex
Full name of responsible person
Nima Mousavi Darzikolaee
Position
Resident of Radiation Oncology
Other areas of specialty/work
Street address
Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran
City
Tehran
Postal code
1419733141
Phone
+98 21 6694 8679
Fax
+98 21 6658 1633
Email
mousavi-n@razi.tums.ac.ir
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