

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 study is 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 will 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 metastatic 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 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

Person responsible for updating data

Contact

Name of organization / entity

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

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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