

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the Efficacy of Venlafaxine and Duloxetine in Improving Chemotherapy-Induced Neurotoxicity in Cancer Patients

Protocol summary

2023-02-15, 1401/11/26

Study aim

Determining the Effectiveness of Venlafaxine and Duloxetine in Improving chronic neurotoxicity induced by Chemotherapy in Cancer Patients

Design

The Admitted patients Were divided into two groups of 15 people based on Balanced Balance Randomization. The first group was treated with venlafaxine and the second group was treated with duloxetine.

Settings and conduct

Oncology Department Of Rasoul Akram Hospital

Participants/Inclusion and exclusion criteria

Condition for Entering the Study: Age 18 to 75 Years, Incidence of Neuropathy after Starting Chemotherapy, Cancer Diagnosis, Receive Chemotherapy; Non_Entry Condition: Having an Underlying Neuropathy Disease Such as Diabetes Mellitus, Incomplete Treatment, Intolerance of The Patient due to Drug Side Effects, Death of Patients

Intervention groups

Cancer Patients Undergoing Chemotherapy Regimen as Outpatient or Inpatient

Main outcome variables

Sex, Age, Treatment Group, Peripheral Neuropathy, Severity of Neuropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230201057300N1**

Registration date: **2023-02-15, 1401/11/26**

Registration timing: **retrospective**

Last update: **2023-02-15, 1401/11/26**

Update count: **0**

Registration date

Registrant information

Name

Hanzaleh Jourebrahimian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5422 8717

Email address

h.jourebrahimian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-14, 1397/01/25

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

2018-04-17, 1397/01/28

Actual recruitment end date

2019-04-13, 1398/01/24

Trial completion date

2019-04-13, 1398/01/24

Scientific title

Comparison of the Efficacy of Venlafaxine and Duloxetine in Improving Chemotherapy-Induced Neurotoxicity in Cancer Patients

Public title

The Efficacy of Venlafaxine and Duloxetine in Improving Chemotherapy-Induced Neurotoxicity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 75 years Incidence of Neuropathy after starting Chemotherapy Cancer Diagnosis Receive

Chemotherapy
Exclusion criteria:
Having an Underlying Neuropathy Disease such as
Diabetes Mellitus Incomplete Treatment Intolerance of
the patient due to Drug side effects Death of Patients

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced Balance Randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical
Sciences

Street address

No. 77, Shahid kismoradi Ave., Shahid Shiroudi Blvd.,
Tonekabon Town

City

Tonekabon

Province

Mazandaran

Postal code

4681947170

Approval date

2017-05-28, 1396/03/07

Ethics committee reference number

Ir. IUMS. FMD. rec. 1397.305

Health conditions studied

1

Description of health condition studied

Chemotherapy-Induced Peripheral Neuropathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of Peripheral Neuropathy

Timepoint

Severity of Peripheral Neuropathy at the Beginning of the
study then weekly

Method of measurement

NCI- Common Terminology Criteria for Adverse Event-
ver3

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The First Group Was Treated With
Venlafaxine at 37.5 mg Daily and Increased to 75 mg if
The Patient Tolerated. The Second Group Was Treated
With Duloxetine at 30 mg Daily and Increased to 60 mg
Daily. The Treatment Will Last Up to 10 Weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Farshid Fardad

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No. 77, Shahid kiamoradi Ave., Shaid Shiroudi Blvd.,
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Email

h.jourebrahimian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farshid Fardad

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Farshid Fardad

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Full name of responsible person

Farshid Fardad

Position

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Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Hanzaleh Jourebahimian

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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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