

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Assessment of the effect of memantine in the treatment of chemotherapy-induced peripheral neuropathy: double-blind randomized clinical trial

Protocol summary

Study aim

Evaluation of the effects of memantine on the symptoms of peripheral neuropathy induced by chemotherapy drugs

Design

The study, which will be performed as a double-blind clinical trial, 180 patients with cancer candidate chemotherapy will be divided into two experimental (n = 90) and placebo (n = 90) groups based on a random number table. The experimental group will receive memantine and the second will receive placebo.

Settings and conduct

After randomly assigning individuals to groups, their neuropathy will be assessed. Demographic information, type of cancer & treatment, duration of chemotherapy, etc. will be recorded. The drug is started at a dose of 5 ml and continued with 20 ml. The duration of medication for both groups will be 8 weeks. Finally, participants' neuropathy will be examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with any malignancy seek chemotherapy with grade 2 neuropathy or higher.
Exclusion criteria: Patients with hypertension, acute heart failure, diabetes (types 1 and 2), peripheral vascular patients, amantadine, ketamine, L-dopa, anticholinergic agonists, barbiturates, neuroleptics, IMAO, antispasmodics Baclofen, phenytoin, hydrochlorothiazide and warfarin

Intervention groups

The first group as the experimental group includes patients receiving memantine. The second group will be considered as the placebo group, which will include patients receiving placebo.

Main outcome variables

Chemotherapy induced peripheral neuropathic pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160310026998N12**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **prospective**

Last update: **2020-08-19, 1399/05/29**

Update count: **0**

Registration date

2020-08-19, 1399/05/29

Registrant information

Name

Saba Ghaffary

Name of organization / entity

Faculty of Pharmacy, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 33266042

Email address

ghaffarys@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of memantine in the treatment of chemotherapy-induced peripheral neuropathy: double-blind randomized clinical trial

Public title

Assessment the effect of memantine in the treatment of chemotherapy-induced peripheral neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with any malignancy who have had grade 2 or higher neuropathy following chemotherapy

Exclusion criteria:

Patients with hypertension Acute heart failure type 1 & 2 diabetes mellitus peripheral vascular disease 285/5000Patients taking drugs (amantadine, ketamine, dextromethorphan, L-dopa; dopaminergic, anticholinergic agonists, barbiturates, neuroleptics, IMAO, antispasmodics, dantrolene or baclofen, phenytoinquinotone, cimetidine, ranitidine And warfarin) alcohol use People of reproductive ages, pregnancy and lactation People taking other neuropathic medications such as gabapentin, pregabalin and dologestin Patients with brain or leptomeningeal metastasis

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

180 patients with cancer who are candidates for chemotherapy treatment and referred to the clinic or hospital ward of Shahid Ghazi Hospital will be screened and will select by including & excluding criteria. Patients will then be divided into two groups through simple randomization procedure based on a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients with a variety of cancers, who will be candidates for the study based on the including & excluding criteria , will enter the study after completing informed consent, but will not be aware of the main drug or placebo. Also, physicians assisting the researcher who prescribe the drug, will not inform the type of main drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee at Tabriz University of Medical Sciences

Street address

Shahid Ghazi hospital, Tabriz University of Medical Sciences, Daneshgah street

City

tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.TBZMED.REC.1399.211

Health conditions studied**1****Description of health condition studied**

chemotherapy-induced peripheral neuropathy in patients with cancer

ICD-10 code

G90.0

ICD-10 code description

Idiopathic peripheral autonomic neuropathy

Primary outcomes**1****Description**

severity of neuropathic symptoms

Timepoint

At PRE intervention (baseline phase) & 8 weeks after intervention

Method of measurement

McGill pain questionnaire, Neuropathic Pain, Neuropathic Pain Symptom Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients undergoing chemotherapy with symptoms of peripheral neuropathy first receive memantine at a dose of 5 mg for three days, and every three days 5 mg is added to the previous dose, and finally at a dose of 20 mg, treatment will continue for eight weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients undergoing chemotherapy with symptoms of peripheral neuropathy as a placebo group will receive placebo for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ghazi Hospital in Tabriz, Iran

Full name of responsible person

Saba Ghaffary

Street address

Shahid Ghazi hospital, Tabriz University of Medical Sciences, Daneshgah street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Central building of Tabriz University of Medical Sciences, Goltasht boulevard, Azadi street

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

saba Ghaffary

Position

Assistant Professor of Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Full name of responsible person

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

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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