

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The study of efficacy of memantin on neuropathy in diabetic patients- double blind randomized clinical trial

#### Protocol summary

##### Study aim

The study of efficacy of memantin on neuropathy in diabetic patients

##### Design

a randomized double-blind, clinical trial

##### Settings and conduct

This study is conducted on 100 patients with Diabetic neuropathy (DN). The patients were randomly divided into two groups of control and intervention. In the test group, memantine was coadministered with other drugs administered in the first week at a dose of 5 mg twice daily and from the second week to the eighth week a dose of 10 mg and twice daily is given twice a day. In the control group, other commonly prescribed drugs other than memantine are prescribed to the patient. After completing the questionnaire and three monofilament, warm-cold, and diaphasal tests, in order to diagnose the presence of neuropathy, the researcher performed the efficacy of memantine in controlling pain. Will take.

Endocrinology Clinic of Tabriz Imam Reza Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic neuropathy (PDN) aged between 18 and 75 years who have been diagnosed with PDN due to physical examinations. And patients treated with gabapirzin (gabapentin and pregabalin) Exclusion criteria: pregnancy- Lactation- Cardiovascular disease- The absence of other neuropathies, such as neuropathy caused by herpes and trigeminal neuralgia, and ...- Sensitization to memantine or other formulation components Uncontrolled hypertension- Epilepsy- Liver failure- Renal insufficiency with creatinine clearance less than 30 ml / min

##### Intervention groups

Intervention group: received memantine 5 mg twice daily in the first week and received memantine 10 mg from week 2 to week 8 twice daily

##### Main outcome variables

Fasting blood sugar level, Glycosylated hemoglobin

(three months sugar)(A1C), Heat and cold test, diapazon test, monofilament test, Pain and numbness on the soles of the feet and hands

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180404039187N5**

Registration date: **2019-09-05, 1398/06/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-05, 1398/06/14**

Update count: **0**

##### Registration date

2019-09-05, 1398/06/14

##### Registrant information

##### Name

Elnaz Shaseb

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1337 2250

##### Email address

shasebe@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-15, 1398/02/25

##### Expected recruitment end date

2019-11-22, 1398/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The study of efficacy of memantin on nouropathy in diabetic patients-double blind randomized clinical trial

**Public title**  
Evaluation of the effect of memantine on diabetic neuralgia(diabetic nouropathy)(DN)

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with diabetic neuropathy (PDN) aged between 18 and 75 years who have been diagnosed with PDN due to physical examinations. And patients treated with gababirzin (gabapentin and pregabalin)  
**Exclusion criteria:**  
Pregnancy- Lactation- Cardiovascular disease- The presence of other neuropathies, such as neuropathy caused by herpes and trigeminal neuralgia, and ...- Sensitization to memantine or other formulation components- Uncontrolled hypertention- Epilepsy- Liver failure- Renal insufficiency with creatinine clearance less than 30 ml / min

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

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number to each of them AABB(1) ABAB(2) ABBA(3) BBAA(4) BABA(5) BAAB(6) 3) Choosing random numbers between 1 and 6 4) Defining the treatment assignment list For example: AABB(1)\_BBAA(4)\_ABAB(2)\_BABA(5)

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The participants (patients) and the researcher who have the task of sampling in the study are all blind during the study. At the patient's level, blindness will be done as the patients do not know in which group (control or intervention group) they are in. The researcher on the basis of lable A or B without knowing the nature of A, B and according to the randomized list will give the medicine to pateints or not.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

#### Approval date

2019-06-11, 1398/03/21

#### Ethics committee reference number

IR.TBZMED.REC.1398.232

## Health conditions studied

### 1

#### Description of health condition studied

diabetic nouropathy

#### ICD-10 code

E11.42

#### ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

## Primary outcomes

### 1

#### Description

Fasting blood sugar level

#### Timepoint

At the beginning and 3 months after intervention

#### Method of measurement

Enzymatic method with Pars Azmoon kit

### 2

#### Description

Glycosylated hemoglobin (three months sugar)(A1C)

#### Timepoint

At the beginning and 3 months after intervention

#### Method of measurement

Immunoturbidimetry autoanalyzers assay

### 3

#### **Description**

Heat and cold test

#### **Timepoint**

At the beginning and 3 months later

#### **Method of measurement**

Using a thermophile tool (Diagnostic Tool for Neuropathy)

### 4

#### **Description**

diapazon test

#### **Timepoint**

At the beginning and 3 months later

#### **Method of measurement**

Using Diapazone (Diagnostic Tool for Neuropathy)

### 5

#### **Description**

monofilament

#### **Timepoint**

At the beginning and 3 months later

#### **Method of measurement**

Using a monofilament device (a diagnostic tool for neuropathy)

### 6

#### **Description**

Pain and numbness on the soles of the feet and hands

#### **Timepoint**

At the beginning and 3 months later

#### **Method of measurement**

DN4 questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: received memantine 5 mg twice daily in the first week and received memantine 10 mg from week 2 to week 8 twice daily

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: routin care which includes Cap Gabapentin 300 mg once daily at night.

#### **Category**

Diagnosis

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Endocrinology Clinic of Imam Reza Teaching Hospital

##### **Full name of responsible person**

Elnaz Shaseb

##### **Street address**

Imam Reza Hospital, Golgasht Ave., Azadi Ave.

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

59-3347054

##### **Phone**

+98 41 3334 7054

##### **Email**

info@imamreza.tbzmed.ac.ir

##### **Web page address**

<https://imamreza.tbzmed.ac.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

ابوالقاسم جويبان

##### **Street address**

No. 2, Central Building, Tabriz University of Medical Sciences, Golgasht Ave., Azadi Ave.

##### **City**

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##### **Fax**

+98 41 3335 9680

##### **Email**

Jouyban@tbzmed.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **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**

Elnaz Shaseb

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Pharmacy, Tabriz university of Medical Science, Golgaste Ave., Azadi Ave.

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Elnaz Shaseb

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Elnaz al.sadat Jafarzadeh chehraghi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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jafarzadeelnaz042932@gmail.com

**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