Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim
The study of efficacy of memantin on nouropathy in diabetic pations

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 monophilaman, 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 gababirzin (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 hypertention- Epilepcy- Liver failure- Renal insufficiency with creatinine clearance less than 30 ml / min

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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)

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+98 41 1337 2250

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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- Epilepcy- 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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
ابوالقاسم جویبان
Street address
No. 2, Central Building, Tabriz University of Medical Sciences, Golgasht Ave,. Azadi Ave.
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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
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

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

Student

Latest degree

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Other areas of specialty/work

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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