Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Comparison the efficacy of Duloxetine versus Gabapantin in patients with painful diabetic peripheral neuropathy

Protocol summary

Study aim
Comparison the efficacy of Duloxetine versus Gabapantin in patients with painful diabetic peripheral neuropathy

Design
This clinical trial study includes two groups of control and intervention with double-blind parallel groups, randomized using four-block method. The trail phase is 3.

Settings and conduct
A total of 104 patients admitted to the neurology clinic of Ahwaz Golestan Hospital with diagnosis of diabetic peripheral neuropathic pain (DPNP) and meet the inclusion criteria of study are randomly divided into A and B groups (each containing 52 subjects) using four-block method. Control or A group receives gabapentin and intervention B group receives duloxetine. Group A receives 300 mg oral gabapentin daily, and if the patients tolerate, dose increase by 300 for three days and reach to maximum dose of 900 mg daily. The group B receives 30 mg oral duloxetine daily, and if patients tolerate, dose increase to 60 mg daily after one week. Duration of treatment in both groups is 8 weeks. The pain level is assessed by visual analogue scale (VAS) before the start of medicine therapy and at the end of week 1, 4 and 8 and sleep interference score clinical global impression of change (secondary effect) are measured. Patients are evaluated by a researcher who has no information on patients treatment group. Both medicines are uniform in terms of appearance and provide for interviewer in pockets labeled A and B (each pocket contained adequate number of medicines for research period).

Participants/Inclusion and exclusion criteria
Patients referring to Neurology clinic of Golestan Hospital of Ahwaz with diagnosis of painful neuropathic diabetes (DPNP)

Intervention groups
Control group receive gabapentin and the intervention group receive duloxetine (DLX)

Main outcome variables
visual analogue scale (VAS) for pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161023030455N2**
Registration date: **2018-08-06, 1397/05/15**
Registration timing: **retrospective**

Last update: **2018-08-06, 1397/05/15**
Update count: **0**

Registration date
2018-08-06, 1397/05/15

Registrant information

Name
Hosein Kaveiani

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Dr. ABIDI pharmaceutical laboratory company and Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-07-06, 1397/04/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the efficacy of Duloxetine versus Gabapantin in patients with painful diabetic peripheral neuropathy

Public title
Comparative efficacy of Duloxetine versus Gabapantin in patients with painful diabetic peripheral neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
aged>18 rule out other DDx. for peripheral neuropathy do nt use drug for treatment of DPNP duration of diabetes ranging from 1 to 15 years HbA1C less than 10 mg A pain score of at least 40 mm on the 100 mm visual analogue scale (VAS)
Exclusion criteria:
patients who were already on other medication for the treatment of DPNP one week prior to the study enrolment hepatic failure; ;renal failure with GFR<30 ml/min concurernt of psycologic disoeder cardiac arhythmia patients with established neuropathy due to other causes;, history of epilepsy drug abuse uncontoroled acute close angle Glocoma recent MI patients who did not give written informed consent pregnant or lactating women
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
Four block
Blinding (investigator's opinion)
Double blinded
Blinding description
First, medicines are uniformed by a physician who is not involved in data collection or analysis. Then, these medicines are provided for researcher as medicines A and B. The complications of both medicines are explained for each of them. They are informed that they can receive any of the medications randomly and written consent is taken from them. Then, medicines are given randomly to patients by one who is responsible for data collection. Another person analyzes the data.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences Department of Neurology
Street address
Ahvaz Jundishapur University of Medical Sciences Department of Neurology, Golestan st.
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2016-05-27, 1395/03/07
Ethics committee reference number
IR.AJUMS.REC.1395.78

Health conditions studied

1

Description of health condition studied
painful diabetic peripheral neuropathy
ICD-10 code
G63.2
ICD-10 code description
Diabetic polyneuropathy

Primary outcomes

1

Description
pain
Timepoint
Before treatment and 1,4 and 8 weeks after treatment
Method of measurement
visual analogue scale

Secondary outcomes

1

Description

Sleep quality

Timepoint

Before treatment and 1,4 and 8 weeks after treatment

Method of measurement

Sleep interference score

2

Description

Changes in clinical status

Timepoint

1,4and 8 weeks after treatment

Method of measurement

Clinical Global Impression of Change

Intervention groups

1

Description

The gabapentin group receives the gabapentin at a dose of 300 mg per day. Then, the dose of 300 mg increases every three days to reach 900 mg per day (300 mg three times per day) and treatment continues for up to 8 weeks.

Category

Treatment - Drugs

2

Description

Duloxetine (DLX) group: this group receives Duloxetine at dose of 30 mg per day before bedtime, and after one week, it increases to 60 mg per day if patient tolerates, and treatment continues for up to 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurologic clinic of Golestan hospital

Full name of responsible person

Hosein Kaveiani

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Golestan. Golestan hospital, Neurologic clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences Department of Neuro

Full name of responsible person

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Grant name

پژوهشی

Grant code / Reference number

Research

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

Yes

Title of funding source

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences Department of Neuro

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

Ahvaz University of Medical Sciences

Full name of responsible person

Hosein Kaveiani

Position

Neurology resident

Latest degree

Medical doctor

Other areas of specialty/work
Neurology
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Person responsible for scientific inquiries

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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable