

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparing the efficacy of Duloxetine with High tone diabetic peripheral neuropathic pain

Protocol summary

Study aim

Comparison of the effectiveness of High tone and deluxin on diabetic neuropathy

Design

Clinical trial with two intervention groups, with parallel groups, double-blind, randomized, phase 3 on 30 patients. Excel software rand function was used for randomization.

Settings and conduct

The present clinical trial was performed on patients with diabetic neuropathy in the neurology ward of Ahvaz Hospital. Block randomization methods were used. The size of the block was four and in each block 2 people in group A and 2 people in group B were assigned. The order of groups A and B within each block was determined randomly using function (RAND) in Excel software. The patients, the intervener, and the person reviewing the results did not know what group the individuals were in, and the study would be conducted in a two-way blind. Group A included patients who were treated with High tone for 30 minutes every 6 weeks and every other day. Group B patients received a daily dose of 60 mg deloxetine for 6 weeks

Participants/Inclusion and exclusion criteria

Age over 18 years Type 1 and 2 diabetes 24-hour mean pain score based on VAS pain visual scale > 4mm exclusion criteria: Mood Disorder, Disseminated anxiety disorder, Avoid substance use, A history of less than a year or more than 15 years of diabetes, Receive medication to control diabetic polyneuropathy within 2 weeks before starting the study, Existence of neuropathy due to another, Peripheral vascular disease, Pregnant or lactating women, History of epilepsy, Uncontrolled acute angle-closure glaucoma, GFR less than 32 mmol / min, Liver disease, Heart disease

Intervention groups

Group A included patients who were treated with High tone for 30 minutes every 6 weeks and every other day Group B patients received a daily dose of 60 mg

deloxetine for 6 weeks

Main outcome variables

Painful vision scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200827048547N1**

Registration date: **2020-09-14, 1399/06/24**

Registration timing: **retrospective**

Last update: **2020-09-14, 1399/06/24**

Update count: **0**

Registration date

2020-09-14, 1399/06/24

Registrant information

Name

Zohre Ghafuri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

zohre.ghafury@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-28, 1398/06/06

Expected recruitment end date

2020-03-13, 1398/12/23

Actual recruitment start date

2019-11-06, 1398/08/15

Actual recruitment end date

2020-05-12, 1399/02/23
Trial completion date
 2020-07-15, 1399/04/25

Scientific title
 Comparing the efficacy of Duloxetine with High tone diabetic peripheral neuropathic pain

Public title
 Evaluation of High tone and Duloxetine on diabetic neuropathy

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years Type 1 and 2 diabetes 24-hour mean pain score based on VAS pain visual scale > 4mm
Exclusion criteria:
 Mood Disorder Disseminated anxiety disorder Avoid substance use A history of less than a year or more than 15 years of diabetes Receive medication to control diabetic polyneuropathy within 2 weeks before starting the study Existence of neuropathy due to another Peripheral vascular disease Pregnant or lactating women History of epilepsy Uncontrolled acute angle-closure glaucoma GFR less than 32 mmol / min Liver disease Heart disease

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: **30**
 Actual sample size reached: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Patients were divided into two groups A and B. Block randomization methods were used. The size of the block was four and in each block 2 patient in group A and 2 patient in group B were assigned. The order of groups A and B within each block was determined randomly using function (RAND) in Excel software.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 This study is a double blind study; In this study, the subject and the researcher are both unaware of the type of treatment used for the patient. Medications are delivered in uniform packages with a code specified by a third party and the information on the number of medications used by the therapist will not be visible. For the high tone procedure, it was performed on the patient

by a third party.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 thics committee of Ahwaz Jundishapur University of Medical Sciences (AJUMS)
Street address
 Khuzestan Province, Ahvaz
City
 Ahvaz
Province
 Khouzeestan
Postal code
 6135715794

Approval date
 2020-01-18, 1398/10/28

Ethics committee reference number
 IR.AJUMS.REC.1398.776

Health conditions studied

1

Description of health condition studied
 Diabetic neuropathy

ICD-10 code
 E13.40

ICD-10 code description
 Other specified diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description
 Painful vision scale

Timepoint
 During the study and on a weekly basis

Method of measurement
 VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A In the high tone treatment group, it was done three times a week. In this method, therapeutic electrodes were implanted in the femoral muscles and 230V muscle stimulation was performed with a stimulation duration of 4 seconds, which is about 10 minutes per day, the number of sessions is about 10 sessions. And the patient's examinations and the amount of pain reduction of the patient are done weekly and are recorded in the relevant table and chart.

Category

Treatment - Drugs

2

Description

Intervention group: Group B In the treatment with Duloxetine (Abidi Company), treatment with this drug is done once a day and weekly monitoring of patients with examinations and evaluation of pain relief and in case of non-response to drug treatment to 30 mg twice, . Increased per day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Mehrnoosh Zakerkish

Street address

Ahvaz, Farvardin Blvd., Golestan hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Grant name

Vice Chancellor for Research, School of Medicine, Ahvaz University of Medical Sciences. Dr. Mohammad Badavi

Grant code / Reference number

D-9811

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

There is no further information

When the data will become available and for how long

There is no further information

To whom data/document is available

There is no further information

Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

There is no further information

What processes are involved for a request to access data/document

There is no further information

Comments