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

Khouzestan

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

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3374 3001

Email
Golestanjpsital@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mohammad Badavi

Street address
Ahvaz, Golestan Boulevard

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3374 3001

Email
Info@Ajums.Ac.Ir

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

Street address
Ahvaz, Golestan Boulevard

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3374 3001

Email
zohre.ghafury@gmail.com

Person responsible for scientific 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
Street address
Ahvaz, Golestan Boulevard
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3001
Email
zohre.ghafury@gmail.com

Person responsible for updating data

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
Street address
Ahvaz, Golestan Boulevard
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3001
Email
zohre.ghafury@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
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