

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Compare the efficacy of duloxetine and nortriptyline on patients pain with painful diabetic peripheral neuropathy

Protocol summary

Summary

After obtaining written informed consent from eligible patients, and getting an approval from Ethics committee of Ahvaz Jundishapur University of Medical Sciences, a prospective, randomized study will be done with the aim of Compare the efficacy of duloxetine and nortriptyline on patients pain with painful diabetic peripheral neuropathy. This study will be conducted on 122 patients in Golestan Hospital Endocrinology Clinic in Ahvaz City in 2016 year. Inclusion criteria including age greater than 18 years; diabetes type one or two; 24-hour average pain score greater than 40 millimeter; Michigan neuropathy screening instrument scores by at least 3; and electrophysiological findings indicate neuropathy. Exclusion criteria including mood disorder; drug and alcohol abuse; history of epilepsy; pregnant women; peripheral vessels disease; and history of diabetes less than a year. Patients will be randomly allocated into two groups according to table of random numbers. Groups "one" and "two" will receive 30 milligram of duloxetine capsule orally every day for six weeks and 25 milligram of nortriptyline capsule orally every day for six weeks, respectively. Neuropathic pain with visual analogue scale and drugs side effects will measure every week for six weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031927107N1**

Registration date: **2016-04-21, 1395/02/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-04-21, 1395/02/02

Registrant information

Name

Fatemeh Amiri

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-01-04, 1395/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the efficacy of duloxetine and nortriptyline on patients pain with painful diabetic peripheral neuropathy

Public title

Compare the effect of duloxetine and nortriptyline on diabetics pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age greater than 18 years; diabetes type one or two; 24-hour average pain score greater than 40 millimeter; Michigan neuropathy screening

instrument scores by at least 3; and electrophysiological findings indicate neuropathy Exclusion criteria: Mood disorder; drug and alcohol abuse; history of epilepsy; pregnant women; peripheral vessels disease; and history of diabetes less than a year

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study patients will be randomly allocated into two groups according to table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Ethics Committee

City

Ahvaz

Postal code

6135715794

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

IR.AJUMS.REC.1394.567

Health conditions studied

1

Description of health condition studied

Diabetic Polyneuropathy

ICD-10 code

G63.2

ICD-10 code description

Diabetic Polyneuropathy

Primary outcomes

1

Description

Pain

Timepoint

Every week for six weeks

Method of measurement

visual Analogue Scale Questionnaire

Secondary outcomes

1

Description

Drugs side effects

Timepoint

Every week for six weeks

Method of measurement

Questionnaire

Intervention groups

1

Description

Duloxetine: Dose: 30 mg; Number of using: Forty-two times(once a day); Factory name: Tadbir Kalay-e Jam Company; Manufacturing Country's Name: Iran; Administration: Orally; Administration time: Every day

Category

Treatment - Drugs

2

Description

Nortriptyline: Dose: 25 mg; Number of using: Forty-two times(once a day); Factory name: Daroupakhsh Company; Manufacturing Country's Name: Iran; Administration: Orally; Administration time: Every day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital Endocrinology Clinic

Full name of responsible person

Mehrnoush Zakerkish

Street address

Endocrinology Clinic, Golestan Hospital, Golestan Ave

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Mostafa Fegghi

Street address

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Science, Golestan Ave

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Fatemeh Amiri

Position

Resident

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty