Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Amitriptyline versus Carbamazepine in treatment of painful diabetic neuropathy

Protocol summary

Summary

The purpose of this study was to compare Amitriptyline versus Carbamazepine in the treatment of painful diabetic neuropathy. A total of 60 patients with type 2 diabetes were randomly assigned to receive Amitriptyline, 50 mg/d or Carbamazepine, 200mg, TDS, for six weeks, in a double blind trial. Intensity of pain was evaluated based on brief pain inventory before the study and six weeks after administration of drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905024435N1**
Registration date: **2010-12-24, 1389/10/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-12-24, 1389/10/03

Registrant information

Name

Reza Haj Manouchehri

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3012

Email address

h.manouchehri@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundi Shapour Medical Sciences University

Expected recruitment start date

2009-08-23, 1388/06/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Amitriptyline versus Carbamazepine in treatment of painful diabetic neuropathy

Public title

Amitriptyline versus Carbamazepine in the treatment of painful diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-65 y/o, confirmed diabetic neuropathy with EMG/NCV Exclusion criteria: pregnancy, breast feeding, recent MI, allergy to drugs, past hx. of seizure, mood disorder, diabetic cystopathy or gastroparesis, renal or hepatic failure, hypothyroidism.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundi Shapour Medical Sciences University

Street address

Ahvaz

City

Ahvaz

Postal code

Approval date

2009-11-22, 1388/09/01

Ethics committee reference number

3353/20/8/پ

Health conditions studied

1

Description of health condition studied

painful diabetic neuropathy

ICD-10 code

E10

ICD-10 code description

Diabetic polyneuropathy

Primary outcomes

1

Description

painful neuropathy

Timepoint

6 weeks

Method of measurement

brief pain inventory (quantitative scale)

Secondary outcomes

1

Description

drugs complications

Timepoint

6 weeks

Method of measurement

by history and assessment

Intervention groups

1

Description

Amitriptyline, 50 mg/day (daroupakhsh) for 6 weeks

Category

Treatment - Drugs

2

Description

Carbamazepine, 600 mg/day (Sobhan darou) for six weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Street address

Golestan Avenue, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Research deputy of Ahvaz Jundishapour University of Medical Sciences

Street address

Golestan avenue

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapour 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 Jundishapour University of Medical Sciences

Full name of responsible person
Reza Haj Manouchehri

Position
Resident of neurology

Other areas of specialty/work

Street address
Neurology department, Golestan hospital, Golestan avenue

City
Ahvaz

Postal code

Phone
+98 61 1374 3012

Fax

Email
h.manouchehri@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person
Dr. Nastaran Majdinasab

Position
Neurologist

Other areas of specialty/work

Street address
Neurology department, Golestan hospital, Golestan Avenue

City
Ahvaz

Postal code

Phone
+98 61 1374 3012

Fax

Email
N.madjdinasab@gmail.com

Web page address

Person responsible for updating data

Contact

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