

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effects of botulinum toxin type A injections on pain symptoms, quality of life and sleep quality of patients with diabetic neuropathy : A randomized double-blind clinical trial

Protocol summary

Study aim

The present study was conducted to compare the effect of Botulinum Toxin A on lower limb neuropathic pain, quality of life and sleep in Diabetic neuropathic patients, with a group of them receiving the placebo.

Design

Two study groups of 19 diabetic patients with lower limb neuropathy in each group, with simple randomization, single center

Settings and conduct

At first, 50 patients with sensory and motor complaints were evaluated. Of these, 38 patients with type 2 diabetes aged 40-70 years who admitted to the Diabetes Clinic of AIA Hospital in Rafsanjan, were selected based on criteria. Patients and investigator were blinded to injected material.

Participants/Inclusion and exclusion criteria

Inclusion: Having type 2 diabetes for at least 3 years, being aged 40-70 years, providing a positive response to four or more questions in DN4, and evidence of diabetic neuropathy in lower limb electrophysiological examination. **Exclusion:** who were allergic to BTX-A, those who used other drugs to reduce neuropathic pain or had a history of myasthenia gravis, subjects with muscle weakness, kidney dysfunction, and history of alcohol use, post-operative patients, those who initiated taking medication after the onset of the study, as well as those who developed aminoglycosides or obstructive airway disease

Intervention groups

,100 units BTX-A (Dysport-Ipsen, UK) was dissolved in 1.2 ml of normal saline and intrathecal (intradermal) according to the grid pattern of 12 points (3 × 4) on the foot surface and injected into the subject's leg (8 units out of 12 were injected in each site) In placebo group the same volume of normal saline was injected in 12 points on foot surface.

Main outcome variables

Quality of life :SF-36 standard questionnaire Pain quality and severity :Neuropathic Pain Scale Pain severity :Visual Analogue Scale Sleep Quality :The Pittsburgh Sleep Quality Index .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190129042540N1**
Registration date: **2019-03-12, 1397/12/21**
Registration timing: **retrospective**

Last update: **2019-03-12, 1397/12/21**

Update count: **0**

Registration date

2019-03-12, 1397/12/21

Registrant information

Name

Alireza Vakilian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-06, 1395/10/17

Expected recruitment end date

2018-03-03, 1396/12/12

Actual recruitment start date

2018-02-04, 1396/11/15

Actual recruitment end date

2018-04-04, 1397/01/15

Trial completion date

2018-10-08, 1397/07/16

Scientific title

The effects of botulinum toxin type A injections on pain symptoms, quality of life and sleep quality of patients with diabetic neuropathy : A randomized double-blind clinical trial

Public title

botulinum toxin type A and diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having type 2 diabetes for at least 3 years 40-70 years old providing a positive response to four or more questions in DN4 test evidence of diabetic neuropathy in lower limb electrophysiological examination

Exclusion criteria:

who were allergic to BTX-A using other drugs to reduce neuropathic pain a history of myasthenia gravis subjects with distal muscle weakness kidney dysfunction history of alcohol use post-operative patients who initiated taking medication after the onset of the study who used aminoglycosides peripheral vascular obstructive disease

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization: To randomize individuals, two groups of random number table method was used. Therefore the direction of reading the numbers was chosen towards the right side. Even numbers were considered for the intervention group and odd numbers was considered for the placebo group

Blinding (investigator's opinion)

Double blinded

Blinding description

investigator and patients are blind in this study . Other colleagues such as nurse and who inject Dysport and analyzer are not blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Central Organization of Rafsanjan University of Medical Sciences, Imam Ali Avenue. Rafsanjan .

City

rafsanjan

Province

Kerman

Postal code

7718796755

Approval date

2017-01-01, 1395/10/12

Ethics committee reference number

IR.RUMS.REC.1395.116

Health conditions studied**1****Description of health condition studied**

Diabeticr polyneuropathy

ICD-10 code

E10.42

ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

Primary outcomes**1****Description**

severity of pain

Timepoint

in the beginning of study and 1, 4, 8, and 12 weeks after intervention

Method of measurement

Pain Visual Analogue Scale

2**Description**

quality of life

Timepoint

in the beginning of study and 1, 4, 8, and 12 weeks after intervention

Method of measurement

Short Form-36Quality-of-Life Questionnaire

3

Description

Severity and quality of pain

Timepoint

in the beginning of study and 1, 4, 8, and 12 weeks after intervention

Method of measurement

Neuropathic Pain Scale

4

Description

Sleep quality

Timepoint

in the beginning of study and 1, 4, 8, and 12 weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: Patients receive the Toxin Botulinum A at the 8 units out of 12 points injected in each site according to the grid pattern

Category

Treatment - Drugs

2

Description

Control group: Patients receive the normal saline as the same volume injected in each point according to the grid pattern

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetic clinic of Ali Ibn Abitalib Hospital

Full name of responsible person

Alireza Vakilian

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Ali-Ibn-Abitalib Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Alireza Vakilian

Position

associate professor ,

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We decided to present it in an article.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available