

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of intradermal Dysport injections on painful diabetic polyneuropathy

Protocol summary

Study aim

The effect of intradermal Dysport injections on painful diabetic polyneuropathy

Design

In group D1, 150 units BTX- A solved in 2 ml saline normal 0.9%, injected in 20 points of right foot of patients intradermally and in left foot in 20 points saline normal 0.9% are injected intradermally .In group D2 150 unites of BTX- A solved in 4 ml saline normal 0.9% for each foot 75 units botulinum toxin A in 20 points of soles of each patient injected intradermally. In group N, in 20 points of sole of each patient with 1 cm from each other and in each point 10 units of insulin syringe of saline normal 0.9% is injected.

Settings and conduct

This study was a prospective, randomized study based on three months of follow-up exerted between May 2019 and September 2019. The patients were enrolled from Tehran, Iran in the clinic of pain of Imam Hossein hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diabetic type I or II; bilateral symmetric distal polyneuropathy based on the Douleur Neuropathique 4 (DN4) questionnaire and Nerve conduction velocity (NCV); aged between 40 and 70 years old Exclusion criteria: Patients aged more than 70 years; local infection in lower limbs; lumbar radiculopathy; neurologic or mental deficit; allergy to the botulinum toxin or used NSAIDs or other medications to alleviate the neuropathic pain; history of alcohol or opium consume; renal disease; muscular weakness or atrophy of lower limb; history of myasthenia gravis; use of aminoglycosides; breastfeeding mothers

Intervention groups

All patients were divided randomly into three groups: one group received botulinum toxin A in one foot and saline normal 0.9% in another foot (group D1), another group received botulinum toxin A in both feet (group D2). The other group received saline normal 0.09% in both feet

(group N).

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130518013364N8**

Registration date: **2019-11-29, 1398/09/08**

Registration timing: **retrospective**

Last update: **2019-11-29, 1398/09/08**

Update count: **0**

Registration date

2019-11-29, 1398/09/08

Registrant information

Name

Mehrdad Taheri

Name of organization / entity

Shahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-08-06, 1398/05/15

Actual recruitment start date

2019-05-10, 1398/02/20

Actual recruitment end date

2019-09-16, 1398/06/25

Trial completion date

2019-11-11, 1398/08/20

Scientific title

The effect of intradermal Dysport injections on painful diabetic polyneuropathy

Public title

The effect of intradermal Dysport injections on painful diabetic polyneuropathy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

diabetic type I or II bilateral symmetric distal polyneuropathy based on the Douleur Neuropathique 4 (DN4) questionnaire and Nerve conduction velocity (NCV) aged between 40 and 70 years old

Exclusion criteria:

local infection in lower limbs lumbar radiculopathy neurologic or mental deficit allergy to the botulinum toxin or used NSAIDs or other medications to alleviate the neuropathic pain history of alcohol or opium consume renal disease muscular weakness or atrophy of lower limb history of myasthenia gravis use of aminoglycosides breastfeeding mothers

AgeFrom **40 years** old to **70 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **141**Actual sample size reached: **141****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients are randomly assigned to one of three groups using the simple random sampling with substitution with the help of a random numbers table (Kendall & Smith table).

Blinding (investigator's opinion)

Double blinded

Blinding description

The physician who injects the drug solutions and the one who evaluates the patients in follow-up visits, are different and are blind to the subject. Patients are not aware of injectable drugs.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway, Shahid Beheshti University Of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.SBMU.MSP.REC.1398.028

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

Diabetic polyneuropathy

ICD-10 code

E10.42

ICD-10 code description

Type 1 diabetes mellitus with diabetic polyneuropathy

2**Description of health condition studied**

Diabetic polyneuropathy

ICD-10 code

E11.42

ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

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

Pain

Timepoint

4 weeks

Method of measurement

VAS

2**Description**

Neuropathy Pain Scale (NPS)

Timepoint

4 weeks

Method of measurement

Scores are based on patients responses to questions (NPS)

Secondary outcomes

empty

Intervention groups**1****Description**

First intervention group: group D1, 150 units BTX- A solved in 2 ml saline normal 0.9%, injected in 20 points of right foot of patients intradermally and in left foot in 20 points saline normal 0.9% are injected intradermally

Category

Rehabilitation

2**Description**

Second intervention group: group D2, 150 unites of BTX- A solved in 4 ml saline normal 0.9% for each foot 75 units botulinum toxin A in 20 points of soles of each patient injected intradermally.

Category

Rehabilitation

3**Description**

Control group: group N, in 20 points of sole of each patient with 1 cm from each other and in each point 10 units of insulin syringe of saline normal 0.9% is injected.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein Hospital's pain clinic

Full name of responsible person

Mehrdad Taheri

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziai

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehrdad Taheri

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the initial implications

When the data will become available and for how long

Since 2020

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Mehrdad Taheri tahe.1352@yahoo.com

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

Send a request by e-mail

Comments