

# 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)

##### Phone

+98 21 7756 7840

##### Email address

m.taheri@sbmu.ac.ir

##### 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

**Age**From **40 years** old to **70 years** old**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**Target 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

**Street address**

Shahid Madani street

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 0000

**Email**

m.taheri@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Ali Ziai

**Street address**

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717434

**Phone**

+98 21 2243 9951

**Email**

mpd@sbmu.ac.ir

**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

**Street address**

Shahid Madani street-Imam Hossein Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 0000

**Email**

m.taheri@sbmu.ac.ir

## Person responsible for scientific 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

**Street address**

Shahid Madani street-Imam Hossein Hospital

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+98 21 7343 0000

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m.taheri@sbmu.ac.ir

## Person responsible for updating data

**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

**Street address**

Shahid Madani street-Imam Hossein Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

0098 73430000

**Email**

m.taheri@sbmu.ac.ir

## 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 taheri.1352@yahoo.com

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

Send a request by e-mail

**Comments**