Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation the effect of Botulinum toxin type A Masport 500 injection on improving pain and quality of life in patients with diabetic neuropathy.

Protocol summary

Study aim
Determining the effect of botulinum toxin A injection in improving pain and quality of life in patients with diabetic neuropathy

Design
This clinical efficacy study has a control group in a Double blind, randomized on 30 patients.

Settings and conduct
By using ready-filled syringes and sealed envelopes, the patients, the injecting person, the outcome assessor, the data analyst and the researcher were blinded to the treatment groups and the patients were randomly divided into 2 groups of 15 people (botulinum toxin injection and placebo or normal Saline) will be divided. The place of study will be Mahdieh Hospital in Tehran

Participants/Inclusion and exclusion criteria
People with definitive diagnosis of diabetes with symptoms of diabetic neuropathy, diabetic neuropathy in the plantar area of both feet confirmed by NCV. Suffering from diabetes for at least three years. Consistency of the patient's medication for diabetic neuropathy for at least one month before entering the study .Exclusion criteria:g Having an underlying disease involving the peripheral nerves that causes symptoms similar to diabetic neuropathy in the plantar area. Change in the patient's medication for diabetic neuropathy during at least one month before entering the study History of myasthenia gravis, Allergy to botulinum toxin suffering from kidney disorder,Having a history of alcohol consumption Opioid addiction, Presence of pain with a typical dermatomal pattern caused by radiculopathy

Intervention groups
15 patients with diabetic neuropathy who receive 240 units of botulinum toxin A drug, 15 patients receive placebo with the same amount and method.l

Main outcome variables
Improving pain and quality of life and sleep in patients with diabetic neuropathy.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240116060710N1**
Registration date: **2024-02-02, 1402/11/13**
Registration timing: **prospective**

Last update: **2024-02-02, 1402/11/13**
Update count: **0**

Registration date
2024-02-02, 1402/11/13

Registrant information
Name
yasaman malekzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2273 9373
Email address
yasimalekztaheri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-04-21, 1403/02/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation the effect of Botulinum toxin type A Masport 500 injection on improving pain and quality of life in patients with diabetic neuropathy.

Public title

Evaluation the effect of Botulinium toxin injection on improving symptoms in patients with diabetic neuropathy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diabetic neuropathy in the plantar area of both feet confirmed by NCV. diabetes at least for three years Consistency of the patient's medication for diabetic neuropathy for at least one month before entering the study Filling out a personal consent form to enter the study

Exclusion criteria:

Having an underlying disease involving the peripheral nerves that causes symptoms similar to diabetic neuropathy in the plantar area. Change in the patient's medication for diabetic neuropathy during at least one month before entering the study History of myasthenia gravis Allergy to botulinum toxin kidney dysfunction Having a history of alcohol consumption Opioid addiction Presence of pain with a typical dermatomal pattern caused by radiculopathy Lack of patient consent to participate in the study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Dividing patients into case and control groups based on the block randomization method for all patients in the case and control groups

Blinding (investigator's opinion)

Double blinded

Blinding description

In this clinical trial study, 30 patients with diabetic neuropathy confirmed by electrodiagnostic study and with symptoms of diabetic neuropathy will be included in the study. For the random allocation of people in the study groups (intervention group and control group) using the random allocation or block method randomization will be used. In this method, blocks of 6 (including three people in the intervention group and 3 people in the control group) will be used with a ratio of 1:1. Random Allocation software will be used to generate random sequences. Random allocation concealment method will be used, in this way that the random sequences created in this method, which are identified by the letters a (intervention group) and b (control group), will be recorded on cards and these cards will be sealed inside the envelope. will be placed in order. In order to preserve the created sequence, numbering will also be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder, then according to the order of arrival of the eligible participants, the envelopes will be opened and The assigned group of that participant will be determined

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Shahid Beheshti univercity of medical sciences

Street address

Shahid Beheshti university of medical sciennce ,Yaman Street ,Chamran highway ,Velenjak Tehran, Iran

City

Tehran

Province

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Postal code

1985717443

Approval date

2024-02-20, 1402/12/01

Ethics committee reference number

ir.SBMU.MSP.REC.1402.496

Health conditions studied

1

Description of health condition studied

Diabetic neuropathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain and quality of life and sleep quality of patients

Timepoint

at the begining of the study and in 1-4-8-12 week after

intervention

Method of measurement

Evaluation of changes in scores of VAS, PSQI, SF-36 questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

After covering the perianal bilateral surface of the foot and the front of the ankle with 2% lidocaine ointment, a total of 240 units of botulinum toxin A must be administered (120 units per foot) once intradermal injection in 6 places on the perianal surface of the foot and the front of the ankles(12 points)

Category

Rehabilitation

2

Description

Control group: After covering the perianal surface of the foot and the front of the ankle on both sides with 2% lidocaine ointment, the same amount(240 unit toxin) of normal injectable saline 0.9% is injected intradermally in the same points (6 points 12 points total) on the perianal surface of the foot and ankles

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdyieh Hospital

Full name of responsible person

Masome Bayat

Street address

Mahdiye Hospital Fadaeiane Eslam St ,Shosh squre , Tehran ,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Mahdiye Hospital Fadaeiane Eslam St ,Shosh squre , Tehran ,Iran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Masoon darou

Proportion provided by this source

80

Public or private sector

Private

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

Yasaman malekzade

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All the data of people participating in the study can be shared after de-identifying people.
When the data will become available and for how long
The access period starts one year after the results are published.
To whom data/document is available
The data of this study will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
If the goal of the researchers is to perform a systematic review and meta-analysis on the data, the non-identifiable data of the patients will be provided to the researchers.
From where data/document is obtainable
by sending an e-mail to yasimalekztaher@gmail.com
What processes are involved for a request to access data/document
Sending an email requesting information and explaining the purpose and method of using data.
Comments