Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of botulinum toxin injection in the treatment of neuropathy in ESRD patients

Protocol summary

Study aim
Effect of botulinum toxin on lower limb neuropathy in ESRD patients

Design
Phase III randomized, double-blind, placebo-controlled, parallel-group trial in 60 patients, with 1:1 computer-generated block randomization to Botox or placebo.

Settings and conduct
This is a randomized, double-blind clinical trial in patients with ESRD and lower limb neuropathy. Patients are assigned by blocked randomization to the intervention group (botulinum toxin) or control group (placebo). The study is conducted at Sina Hospital, Tehran University of Medical Sciences, with all procedures, interventions, follow-up, and outcome assessments performed at this center. patients and outcome assessors are unaware of group assignments. Botulinum toxin and placebo injections are identical in appearance, volume, and administration to minimize bias.

Participants/Inclusion and exclusion criteria
Inclusion: ESRD with lower limb neuropathy, ≥18 years, both genders, no botulinum toxin or invasive pain treatment in last 6 months, ≥3 months since RRT start, informed consent. Exclusion: Botulinum toxin allergy, neuromuscular disorder, uncontrolled systemic disease, pregnant/breastfeeding, non-compliance or new treatments, spinal injury/spinal stenosis/stroke, serious botulinum toxin adverse events.

Intervention groups
Intervention group: ESRD patients with lower limb neuropathy receiving a single Dysport botulinum toxin injection (100 units, 50 per limb). Control group: ESRD patients with lower limb neuropathy receiving a placebo (normal saline) injection at the same sites.

Main outcome variables
1.Change in mean pain intensity score based on the Visual Analog Scale (VAS) before and after the intervention 2.Change in mean pain score measured by the McGill Pain Questionnaire (MPQ) before and after the intervention 3.Change in quality of life score measured by the EQ-5D questionnaire before and after the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250503065566N1**
Registration date: **2026-06-13, 1405/03/23**
Registration timing: **retrospective**

Last update: **2026-06-13, 1405/03/23**
Update count: **0**

Registration date
2026-06-13, 1405/03/23

Registrant information

Name
Zahra Shilan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8855 4079

Email address
zahrashilan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2026-04-19, 1405/01/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of botulinum toxin injection in the treatment of neuropathy in ESRD patients

Public title

effect of botulinum toxin on sensory symptoms in Dialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients must have a confirmed diagnosis of ESRD, verified by a nephrology specialist based on clinical and laboratory criteria. Age over 18 years, both genders included. Presence of lower limb peripheral neuropathy symptoms, including pain, burning, numbness, or sensory loss. No botulinum toxin injections or other invasive treatments for neuropathic pain in the past 6 months. At least 3 months since starting renal replacement therapy (RRT). Provided informed consent to participate in the study.

Exclusion criteria:

History of hypersensitivity or allergic reaction to botulinum toxin. Presence of neuromuscular disorders such as Myasthenia Gravis or Guillain–Barré Syndrome. Presence of uncontrolled systemic diseases such as malignancy, advanced diabetes mellitus or active infection. Pregnancy or breastfeeding at the time of enrollment . History of spinal cord injury, spinal canal stenosis, or cerebrovascular accident (CVA).

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The unit of randomization in this study is the individual participant. Participants will be allocated to the study groups using block randomization with a 1:1 allocation ratio. The randomization sequence will be generated by computer using statistical software. The randomization sequence will be prepared by an independent researcher who is not involved in participant recruitment, intervention administration, or outcome assessment, in order to minimize selection bias. To ensure allocation concealment, allocation codes will be kept in sequentially numbered, opaque, sealed envelopes and will be opened only after a participant has been definitively enrolled in the study and according to the predetermined sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this trial, blinding will be implemented for participants, outcome assessors, and data analysts. Participants will not be informed whether they receive botulinum toxin or placebo. In addition, the clinician/researcher responsible for clinical assessments and data collection will remain unaware of group allocation. Preparation of syringes containing botulinum toxin or placebo will be performed by an independent researcher who is not involved in outcome assessment or data analysis. Each syringe will be labeled with a unique code and will be identical in appearance and volume to prevent identification of the assigned intervention. The allocation code list will be kept by the independent researcher and will not be disclosed to the study team until completion of data collection. Statistical analyses will be conducted using group codes, and the codes will be unblinded only after the final analysis is completed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tehran University of Medical Sciences

Street address

Tehran, Valiasr Ave., Zarin Alley, Building 16, Apt. 20

City

Tehran

Province

Tehran

Postal code

1511613745

Approval date

2024-07-20, 1403/04/30

Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1404.018

Health conditions studied

1

Description of health condition studied

ESRD

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description
Change in mean pain intensity score based on the Visual Analog Scale (VAS) before and after the intervention.
Timepoint
Patients will be evaluated at four time points: immediately post-injection, one week, six weeks, and three months post-injection.
Method of measurement
Pain intensity will be measured using the Visual Analog Scale (VAS). Patients will record their pain scores at each scheduled time point, and mean scores will be calculated at each time point.

2

Description
Change in mean pain intensity score measured by the McGill Pain Questionnaire (MPQ) before and after the intervention.
Timepoint
Patients will be evaluated at four time points: immediately post-injection, one week, six weeks, and three months post-injection.
Method of measurement
Pain intensity will be measured using the McGill Pain Questionnaire (MPQ). Patients will record their pain scores at each scheduled time point, and mean scores will be calculated at each time point.

Secondary outcomes

1

Description
Change in mean quality of life score based on the EQ-5D questionnaire before and after the intervention.
Timepoint
Patients will be evaluated at four time points: immediately post-injection, one week, six weeks, and three months post-injection.
Method of measurement
Patients' quality of life will be assessed using the EQ-5D questionnaire. Patients will complete the questionnaire at each scheduled time point, and mean scores will be calculated at each time point.

Intervention groups

1

Description
Intervention group: A group of ESRD patients with peripheral neuropathy of the lower limbs who will receive a single session of Dysport Botox injection. The injection dose is 100 units per patient (50 units in the right lower limb and 50 units in the left lower limb), administered subcutaneously in areas with the highest neuropathic symptoms. The injections will be performed by a physical medicine specialist under sterile conditions, and patients will be observed for 30 minutes after injection.
Category
Treatment - Drugs

2

Description
Control group: A group of ESRD patients with peripheral neuropathy of the lower limbs who will receive a normal saline (placebo) injection. The injection will be performed at the same sites and using the same method as the intervention group to ensure identical study conditions. Patients in this group will also be assessed at the same scheduled time points.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Zahra shilan
Street address
Imam Khomeini St., near Hassan Abad Sq.
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2

Recruitment center
Name of recruitment center
Amiralam hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin kordi
Street address
Sina Hospital, Imam Khomeini Street, before Hasanabad Square
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1136746911
Phone
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Email
Zahrashilan@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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Full name of responsible person
Zahra shilan
Position
Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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