Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy of Botulinum Toxin in Managing Chemotherapy-Induced Pain and Paresthesia in Patients with Cancer

Protocol summary

Study aim

Comparison of mean change in pain intensity from baseline to week 4 between the intervention group and the control group

Design

This study is a prospective, randomized, two-arm clinical trial being conducted at Firoozgar and Rasoul-e-Akram hospitals. Patients with chemotherapy-induced neuropathy are enrolled following a clinical assessment and confirmation of the diagnosis via electromyography and nerve conduction studies. The patients' oncological treatments will continue, and any medication adjustments related to the neuropathy will be documented. Sample size: 38 participants (19 per group), accounting for a potential 15% attrition rate.

Settings and conduct

Participants will be identified through referral from oncology clinics. Baseline assessments will be scheduled immediately prior to the first visit and follow-up assessments for outcomes will also be scheduled at weeks 4, 12, and 24 after injection. The study will be single-blinded and the outcome assessor will be blinded to patient group.

Participants/Inclusion and exclusion criteria

Adults 18 to 75 years of age with cancer and history of at least one course of chemotherapy containing a taxane or platinum compounds, at least 6 months since the last dose of neurotoxic chemotherapy(taxane or platinum),not currently receiving neurotoxic chemotherapy

Intervention groups

In the intervention group, patients receive duloxetine along with subcutaneous injections of Dysport®; in the control group, patients receive duloxetine at a daily dose of 30 mg for 24 weeks.

Main outcome variables

Primary outcome — Pain intensity: The intensity of neuropathic pain will be assessed over 24 weeks, using a numerical pain rating scale from 0 to 10. The primary analysis will be based on the change in pain from baseline to week 24.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038619N5**
Registration date: **2026-11-21, 1405/08/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-21, 1405/08/30**
Update count: **0**

Registration date

2026-11-21, 1405/08/30

Registrant information

Name

Katayoun Moradi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of Botulinum Toxin in Managing Chemotherapy-Induced Pain and Paresthesia in Patients with Cancer

Public title
Effect of Botulinum toxin in traetment of neuropathy in patients with cancer

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults aged 18 to 75 years with histopathologically confirmed cancer A history of receiving at least one course of chemotherapy containing a taxane (such as paclitaxel or docetaxel) or a platinum-based agent (such as cisplatin, carboplatin, or oxaliplatin); at least 6 months must have elapsed since the last dose of neurotoxic chemotherapy (taxane or platinum-based agent), and the patient must not currently be receiving neurotoxic chemotherapy. Confirmation of neuropathic pain with a DN4 score ≥ 4. Distal and symmetrical symptoms (in the hands and/or feet) accompanied by positive sensory symptoms (paresthesia, allodynia, painful dysesthesia), confirmed through a clinical examination by a specialist in physical medicine and rehabilitation, as well as by EMG-NCS. The symptoms must have begun during the chemotherapy itself, or at most within 6 months thereafter, and must have persisted for at least 1 month. Stable dosage of medications for neuropathic pain (such as duloxetine or gabapentinoids) from at least 3 weeks prior to the start of the study through the end of week 24. Ability to understand the study process and sign informed consent

Exclusion criteria:
Neuropathies resulting from non-chemotherapy-related causes (e.g., neuropathy associated with uncontrolled diabetes, vitamin B12 deficiency, HIV-associated neuropathy), radiculopathy, or central pain syndromes. Prior receipt of botulinum toxin (any serotype) within the past 6 months, or a known hypersensitivity to the components of BoNT. Neuromuscular junction disorders (e.g., myasthenia gravis, Lambert-Eaton syndrome), clinically significant generalized weakness. Current use of systemic corticosteroids or immunosuppressive drugs. Pregnancy/Breastfeeding Active infection, uncontrolled lymphedema, or skin damage in the limbs intended for injection. Planning for the initiation or modification of systemic medications for CIPN during the study. Coagulation disorders (platelet count < 75 × 10^9/L) or anticoagulant therapy that cannot be safely discontinued for the purpose of administering injections. Life expectancy <12 months due to cancer recurrence or other comorbidities. Cognitive impairment that prevents responding to questionnaires

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
Following successful screening and the signing of an informed consent form, eligible participants will be randomly assigned to either the intervention group (receiving a subcutaneous injection of Dysport®) or the control group (receiving the medication only). Allocation will be performed using variable-sized blocks (ranging from 4 to 6) with a 1:1 ratio to ensure balance between the groups throughout the study. The randomization sequence will be generated by an independent statistician (external to the study execution team) using the R software (via the `blockrand` package). To prevent bias during the recruitment and allocation process, a sealed-envelope method will be employed. Each study enrollment number is linked to a unique code, which is stored in an encrypted file. Once a participant is confirmed as eligible, the corresponding code will be revealed by an independent third party (distinct from the screening team, the injector, and the assessor).

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be conducted as a single-blind study. The outcome assessor, who will collect the questionnaires and record the data, will be blinded to the participants' group allocation (intervention or control). Blinding of the participants and the physician administering the injections will not be possible due to the nature of the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
research ethics committees of school of medicine

Street address
hemmat highway

City
TEHRAN

Province
Tehran

Postal code
1449614535

Approval date
2026-05-14, 1405/02/24
Ethics committee reference number
IR.IUMS.FMD.REC.1405.102

Health conditions studied

1

Description of health condition studied
cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pain intensity
Timepoint
base, 4w, 12w, 24w
Method of measurement
self reported/ NRS

2

Description
paresthesia intensity
Timepoint
base, 4w, 12w, 24w
Method of measurement
Neuropathic Pain Symptom Inventory(NPSI) questoinnere

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, patients receive duloxetine along with subcutaneous injections of Dysport®. The total dose of Dysport is 300 units in 3 mL of normal saline (a concentration of 100 units/mL), administered in a single session via subcutaneous injections into painful areas on the palms or soles. The injections are performed using a 32-gauge needle, following a grid pattern with 1 to 2 cm spacing. Prior to the injections, 2% lidocaine gel is applied to the site for 3 minutes.
Category
Treatment - Drugs

2

Description
Patients in the control and intervention groups receive duloxetine at a daily dose of 30 mg for 24 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Mahdiye ijadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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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Katayoun Moradi

Position
Assistant professor

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Other areas of specialty/work
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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
no further information is available

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
Undecided - It is not yet known if there will be 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