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How botulinum toxin treatment affects people with involuntary neck movements (cervical dystonia)

Submission date
18/10/2025

Recruitment status
Recruiting

Registration date
22/10/2025

Overall study status
Ongoing

Last Edited
22/10/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Some people develop a condition called cervical dystonia, which causes involuntary muscle contractions in the neck. This can lead to abnormal head posture and neck pain. The most effective treatment is injecting botulinum toxin type A into specific neck muscles to help them relax.
This study aims to understand how this treatment affects not just movement and muscle control, but also psychological wellbeing, nervous system function, and certain blood markers. Researchers hope this will improve understanding of how the treatment works and help identify signs that show whether it's working well.

Who can participate?
Adults aged 18–75 years diagnosed with idiopathic cervical dystonia (meaning the cause is unknown) may be eligible to take part.

What does the study involve?
Participants are assessed before and after receiving their usual botulinum toxin treatment. This includes a neurological examination, psychological and nervous system testing, and blood tests to look at biochemical markers.

What are the possible benefits and risks of participating?
There may be no direct benefit to participants, but the results could help improve future treatment and understanding of cervical dystonia. Risks are minimal and mainly related to standard medical procedures like blood tests.

Where is the study run from?
The study is being carried out at the Department of Neurology and Occupational Therapy at the Karol Marcinkowski Medical University in Poznań, Poland.

When is the study starting and how long is it expected to run for?
June 2023 to May 2027

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comprehensive assessment of patients with cervical dystonia treated with botulinum toxin, including neurological examination, functional and neurophysiological tests, radiological findings, serum biochemical concentrations, and neuropsychological tests

Study objectives
The project aimed to comprehensively evaluate patients with dystonia treated with botulinum toxin in the NHF therapeutic program.

Most of the examinations were conducted twice – before and after botulinum toxin administration.

The evaluation included:
1. Neurological examination
2. Functional examination
3. Neurophysiological examination
4. Radiological examination
5. Serum biochemical concentrations
6. Neuropsychological examination

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/06/2023, Bioethics Committee of the Karol Marcinkowski Medical University in Poznań (Bukowska 70, Poznań, 60-820, Poland; +48 (0)618547336; bioetyka.ump@ump.edu.pl), ref: No. 523/2023

Study design
Observational prospective pre–post comparison study

Primary study design
Observational

Study type(s)
Diagnostic, Quality of life, Efficacy

Health condition(s) or problem(s) studied
Idiopathic cervical dystonia

Interventions
The study will involve patients with cervical dystonia receiving standard injection therapy as part of the National Health Fund (NHF) treatment program.

Based on available documentation collected in accordance with the NHF's needs, a selected group of patients meeting the inclusion criteria will be asked about participation in the study following their previous injection.

After obtaining initial consent, they will be informed about the study according to the study protocol and will have time to review it. After providing initial consent, upon arrival for their scheduled treatment, they will be re-reviewed, allowed to ask questions, and required to sign a consent form.

The study will be conducted twice – before the scheduled botulinum toxin administration – in accordance with the NHF program (the toxin doesn't work) and after 4-6 weeks (the toxin works best). The order may be reversed.
Patients will only be observed twice during visits when the toxin has finished its action and when it has its best effect.

The following data and results will be collected:
1. A questionnaire survey to determine age, gender, education, type of work, time of onset of the first symptoms of dystonia, date of diagnosis, comorbidities, and medications used for chronic and acute treatment. Typical scales of CD – classification of Col-Cap and Toronto.
2. Neuropsychological tests to assess cognitive function and assessment of the severity of anxiety disorders, depression, pain, sleep disorders.
3. Functional assessment – mobility and posture examination.
4. Assessment of autonomic nervous system.
5. Blood tests
6. Analysis of radiological examinations routinely performed as part of the mandatory qualification for treatment (MR or CT of the head or neck).
7. Muscle examination using ultrasound.
8. Neurophysiological examination: assessment of muscles in EMG (F and M waves, SSR), CSP (Cutaneous Silence Period).

The collected data will be statistically analyzed and correlated with each other.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Botulinum toxin

Primary outcome(s)
Measured before and after botulinum toxin administration:
1. Neuropsychological tests:
1.1. Cognitive function assessed using the Montreal Cognitive Assessment (MoCA), Mini Mental State Examination (MMSE), ACE-I EpiTrack
1.2. Anxiety disorders assessed using the Liebowitz Social Anxiety Scale
1.3. Depression assessed using the Beck Depression Scale
1.4. Pain assessed using the Numerical Rating Scale (NRS)
1.5. Sleep disorders assessed using the Epworth Sleep Scale
2. Functional assessment – mobility and posture examination:
2.1. Posturography:
2.1.1. Average displacement velocity (anteroposterior [AP] and mediolateral [ML])
2.1.2. Path length
2.1.3. Romberg index
2.1.4. Root mean square (RMS) (AP and ML)
2.2. Up-And-Go Test
2.3. Tinetti test
3. Schellong test:
3.1. Systolic blood pressure (SBP)
3.2. Diastolic blood pressure (DBP)
3.3. Heart rate (HR)
Measured during lying and standing position
4. Laboratory tests: S100 calcium-binding protein B (S100B molecule), neuron-specific enolase (NSE), occludin (OCLN), claudin-5 (CLN5), zonula occludens-1 (zo-1), sPECAM-1, sICAM-1, myoglobin, creatine kinase CK, light neurofilaments, creatinine and eGFR, urea, sodium, potassium, iron, ferritin, blood count
5. Ultrasound of cervical muscles assessed using the Hakkmatt scale
6. Neurophysiological study:
6.1. F wave
6.2. M wave
6.3. Cut. Silent Period
6.4. Symp. Skin. Response

Key secondary outcome(s))
1. Clinical severity of cervical dystonia assessed using the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) before and after botulinum toxin administration
2. Patient-reported quality of life measured using Cervical Dystonia Questionnaire (CDQ-24) before and after botulinum toxin administration

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Ability to provide written informed consent
2. Adults (18–75 years) diagnosed with idiopathic cervical dystonia
3.Eligible for botulinum toxin type A treatment

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Secondary or symptomatic dystonia
2. Other neurological or psychiatric disorders
3. Recent medication changes affecting motor or cognitive function
4. Contraindications to botulinum toxin therapy

Date of first enrolment
26/07/2023

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Poland

Study participating centre
Karol Marcinkowski Medical University in Poznań
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Study participating centre
Municipal Hospital
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Sponsor information

Organisation
Joseph Strus Municipal Hospital

Organisation
Poznan University of Medical Sciences

ROR
https://ror.org/02zbb2597

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data will not be publicly available due to privacy and ethical restrictions. However, anonymised datasets may be shared upon reasonable request to the corresponding author for research purposes consistent with ethical approval.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/08/2025	20/10/2025	Yes	No
Protocol file			22/10/2025	No	No
Protocol file			22/10/2025	No	No