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# The biomechanical effects of botulinum toxin type A on children with cerebral palsy

**Submission date**
17/01/2023

**Recruitment status**
No longer recruiting

**Registration date**
15/03/2023

**Overall study status**
Completed

**Last Edited**
16/07/2025

**Condition category**
Nervous System Diseases

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

## Plain English summary of protocol

Background and study aims
A common treatment option for individuals with spastic cerebral palsy is botulinum toxin type A (BTX-A). BTX-A has been reported as a safe and effective treatment with the ability to enhance performance in school activities, and activities of daily living, particularly in children with mild movement impairments. In a previous study, there was an observation of increased muscle volume in the non-injected muscle and a decreased volume in that of the injected muscle following BTX-A treatment in a population of children with spastic CP. Additionally, it has been found that BTX-A can induce muscle weakness in the injected and non-injected muscles, but there is little knowledge of how the mechanical properties of muscles contribute to this induced muscle weakness. Where a patient may require a tendon transfer surgery, following BTX-A treatment, the properties of the tendons may affect the outcome of surgery, due to the contribution of tendon mechanical properties to force generation of the muscle-tendon unit. This raises the question of how BTX-A-induced adaptations affect the functional ability of the upper limb and how these adaptations may affect the length of treatment. Addressing these questions will give us an idea of when decisions should be made to continue BTX-A treatment or to begin to consider surgical options. Hence, it is important to know if the continuous use of BTX-A affects the performance of tendons in future surgical interventions. Currently, no objective evaluation is done to assess muscle and tendon mechanical properties prior to surgical intervention.

Who can participate?
Children aged between 4 and 18 years old who are diagnosed with spastic cerebral palsy in their upper limb, and are due to start BTX-A treatment for their hand, wrist or forearm

What does the study involve?
The following measurements will be repeated at various times before and after the participant's BTX-A treatment. The first session will be before the start of BTX-A treatment, the second session will be between 3 weeks and 6 months after treatment and the third session will be at least 6 months after treatment. Ultrasound will be used to look at the muscles and tendons in the participant's wrist and forearm, particularly looking at the elastic and architectural properties. To look at how the participant's muscles move, we use electromyography sensors on the participant's wrist and forearm whilst they are performing a series of simple limb

movements. The participant will be asked to perform a series of movements selected from the Shriners Hospital Upper Extremity Evaluation (SHUEE) test.

What are the possible benefits and risks of participating?
There are no direct benefits to the research participants other than taking part in scientific research. The adhesive used to place the EMG sensors on the participants' skin may cause redness. Participants will be informed that if they notice any irritation due to contact with the ultrasound gel or EMG sensor adhesive during or immediately following the study, they should inform the investigators. The area will be cleaned with soap and water. Participants will be informed that if the irritation persists for more than 24 hours, they should inform the investigators of this study so that we may advise them as to whether to consult their local medical clinic. As some physical tasks will be undertaken, the participant may suffer from fatigue. If this happens, the participant should inform the investigators and the tests will stop until the participant feels prepared to continue with the test procedure. If any injuries, illnesses, or accidents should occur, a clinician will be called and all accidents and near misses will be reported.

Where is the study run from?
The study is being run by Imperial College London (UK) and takes place in Chelsea and Westminster Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2019 to June 2024

Who is funding the study?
UK Research and Innovation (UKRI) Engineering and Physical Sciences Research Council (EPSRC)

Who is the main contact?
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# Contact information

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
296396

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
IRAS 296396, CPMS 54295

## Study information

## Scientific Title
The effects of botulinum toxin type A on the biomechanical and elastic properties of muscles and tendons in the upper extremity of children with spastic cerebral palsy

## Acronym
TBEOBOCWCP

## Study objectives
The principal objective of this study is to understand the biomechanical adaptations of the musculoskeletal system following intramuscular botulinum toxin type A (BTX-A) injections in children with upper limb spastic cerebral palsy. This is to better understand its influence on muscle and tendon selection for surgery.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 12/10/2022, HRA and Health and Care Research Wales (HCRW) (Health and Care Research Wales (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)1686 252101, (0)2920 230457, (0)7920 565664; Wales.REC5@wales.nhs.uk), ref: 22/WA/0305

## Study design
Single-centre observational cohort study

## Primary study design
Observational

## Secondary study design
Cohort study

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Observation of botulinum toxin type A in children with upper limb spastic cerebral palsy

## Interventions
The participants will be aged between 4 and 18 years old, will have been diagnosed with spastic cerebral palsy in their upper limb and will be due to start BTX-A treatment for their hand, wrist or forearm. The following measurements will be repeated at various times before and after the participant's BTX-A treatment. The first session will be before the start of BTX-A treatment, the second session will be between 3 weeks and 3 months after treatment and the third session will be at least 6 months after treatment. Ultrasound will be used to look at the muscles and

tendons in the participant’s wrist and forearm, particularly looking at the elastic and architectural properties. To look at how the participant’s muscles move, we use electromyography sensors on the participant’s wrist and forearm whilst they are performing a series of simple limb movements. The participant will be asked to perform a series of movements selected from the Shriners Hospital Upper Extremity Evaluation (SHUEE) test.

### Intervention Type
Other

### Primary outcome measure
Elastic and architectural properties of muscles and tendons in children with upper limb spastic cerebral palsy measured using ultrasound before the start of intramuscular botulinum toxin type A (BTX-A) injections, between 3 weeks and 3 months after treatment and at least 6 months after treatment

### Secondary outcome measures
Muscle activity during the Modified Ashworth scale test measured using electromyography sensors placed on the upper limb before intramuscular BTX-A injections, between 3 weeks and 3 months after treatment and at least 6 months after treatment

### Overall study start date
01/10/2019

### Completion date
30/06/2024

## Eligibility

### Key inclusion criteria
1. Aged between 4 and 18 years old
2. Diagnosed with spastic cerebral palsy in at least one of their upper limbs
3. Due to start BTX-A treatment for their affected upper limb
4. Minimum ability to hold an object and stabilise it for use by the other hand
5. Able to comprehend and complete the test protocol
6. Participant or the participants' parent/carer must be able to speak, read and understand English, in order to be involved in this study

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
4 Years

### Upper age limit
18 Years

### Sex

Both

### Target number of participants
25

### Total final enrolment
8

### Key exclusion criteria
1. Any surgical intervention on the upper extremity in the last 6 months
2. Any known allergy to adhesives
3. Any known skin allergies
4. Unable to obtain informed consent from participant's parent/carer
5. The participant and the participants' parent/carer are not able to speak, read and understand English

### Date of first enrolment
16/05/2023

### Date of final enrolment
21/05/2024

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Chelsea and Westminster Hospital NHS Foundation Trust**
Chelsea & Westminster Hospital
369 Fulham Road
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## Sponsor information

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Imperial College London

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**Sponsor type**
University/education

**Website**
http://www.imperial.ac.uk/

**ROR**
https://ror.org/041kmwe10

# Funder(s)

**Funder type**
Research council

**Funder Name**
Engineering and Physical Sciences Research Council

**Alternative Name(s)**
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/06/2025

## Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol file | version 5 | 07/05/2024 | 27/08/2024 | No | No |
| Basic results | | | 16/07/2025 | No | No |