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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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Additional identifiers

Integrated Research Application System (IRAS)
296396

Central Portfolio Management System (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

Primary study design
Observational

Study design
Single-centre observational cohort study

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Upper age limit
18 Years

Sex
All

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
United Kingdom

England

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
Imperial College London

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, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Basic results			16/07/2025	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 5	07/05/2024	27/08/2024	No	No