Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Functional Outcomes of Botulinum Neurotoxin-A Injection Followed by Reciprocal Electrical Stimulation of Upper-Limb Muscles in Children with Cerebral Palsy

Protocol summary

Study aim
To evaluate the effect of botulinum neurotoxin-A (BoNT-A) injection and reciprocal neuromuscular electrical stimulation (rNMES) and their combination on the upper extremity function in children with spastic hemiplegia

Design
Randomized single-blind controlled clinical trial

Settings and conduct
Department of Physical Therapy and Health Rehabilitation at the College of Applied Medical Sciences, Prince Sattam bin Abdulaziz University, Al-Kharj, Saudi Arabia.

Participants/Inclusion and exclusion criteria
Sixty-four children with CP will be recruited from a large tertiary referring hospital. Children will be included based on the following criteria: 1) diagnosis of spastic hemiplegia, 2) age 6 and 10 years, 3) spasticity of grade II or III according to Modified Ashworth Scale, 4) mental capacity to comply with verbal instructions during evaluation and treatment, 5) normal/corrected visual or auditory function. Children will be excluded based on the following criteria: 1) contractures limiting arm-hand function, 2) history of botulinum toxin-A injection in the involved upper limb, six months before enrollment, 3) history of casting and/or musculoskeletal surgery in the involved upper limb, one year before the study, 4) Uncontrolled seizures.

Intervention groups
Group I; BoNT-A Group II; rNMES Group III; combined BoNT-A and rNMES Group IV; Control

Main outcome variables
Unilateral upper-limb function Bimanual hand function Real-time arm-hand function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200215046504N1**
Registration date: **2020-07-29, 1399/05/08**
Registration timing: **retrospective**

Last update: **2020-07-29, 1399/05/08**
Update count: **0**

Registration date
2020-07-29, 1399/05/08

Registrant information
Name
Ragab Elnaggar
Name of organization / entity
Cairo University
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Egypt
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-01, 1397/05/10

Expected recruitment end date
2018-11-01, 1397/08/10

Actual recruitment start date
2018-08-01, 1397/05/10

Actual recruitment end date
2018-11-01, 1397/08/10

Trial completion date
2019-10-30, 1398/08/08

Scientific title

Functional Outcomes of Botulinum Neurotoxin-A Injection Followed by Reciprocal Electrical Stimulation of Upper-Limb Muscles in Children with Cerebral Palsy

Public title
Neuromuscular blocking/stimulation in cerebral palsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of spastic hemiplegic cerebral palsy age between 6 and 10 years Spasticity grade II or III according to Modified Ashworth Scale mental capacity enabling compliance with evaluation and treatment instructions Normal/corrected visual and auditory function
Exclusion criteria:
Contractures limiting arm-hand function Botulinum toxin-A injection in the involved upper limb in the past six months If children will be advised against stopping spasticity-relieving medications during the study period by their neuro-pediatrician Orthopedic or neuromuscular surgery or casting of the paretic upper limb within 1 year before starting study Uncontrolled seizures
Age
From **6 years** old to **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **56**
Actual sample size reached: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
- Stratified randomization will be used - First, Four strata will be constructed based on participants' age and spasticity level on the Modified Ashworth scale (MAS) as follows: 1- Children ages 6 to 8 and have spasticity level II on MAS 2- Children ages more than 8 to 10 years and have spasticity level II on MAS 3- Children ages 6 to 8 and have spasticity level III on MAS 4- Children ages more than 8 to 10 years and have spasticity level III on MAS - Next, the subjects in each stratum will be concealed in black envelopes. - Then, a random sample, proportional to the stratum size, will be selected by an independent person who will not be a part of the study (physical therapy student) to create four subsamples from each stratum. - Eventually, four subsamples (one from each stratum) will be selected rondomly by the same independent person and will be compiled to form a sample for each group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The rater will be blinded to intervention assignments and will not be part of this research at any stage of its implementation
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Department of Physical Therapy Research Ethics Committee
Street address
Sa'ad Ibn Mu'adh
City
Al-Kharj
Postal code
16278
Approval date
2018-05-23, 1397/03/02
Ethics committee reference number
RHPT/0018/0064

Health conditions studied

1

Description of health condition studied
Cerebral palsy
ICD-10 code
G80
ICD-10 code description
Cerebral palsy

Primary outcomes

1

Description
Unilateral upper-limb function
Timepoint
Pre-treatment, post-treatment, and 6 months after treatment (all completed)
Method of measurement
Melbourne Assessment

2

Description
Bimanual hand function
Timepoint
Pre-treatment, post-treatment, and 6 months after treatment (all completed)
Method of measurement
Assisting Hand Assessment

Secondary outcomes

1

Description
Arm-hand, real-time function
Timepoint
Pre-treatment, Post-treatment, and 6 months post-treatment (all completed)
Method of measurement
Pediatric Motor Activity Log

Intervention groups

1

Description
Intervention group: 1) Children will receive a single set of intramuscular injection of botulinum toxin-A (Botox®, Allergan PLC, Dublin, Ireland). To increase injection tolerance, children will be sedated using oral midazolam (0.5 mg/kg). The dosage will be 0.5-2 U kg-1/muscle group, with a total dosage of 12 U kg-1 (and will never exceed a maximum total dose of 400 U). An ultrasound-guided injection procedure will be used to determine the locations of injection. 2) Children will receive a physical rehabilitation program emphasizing functional strength training, hand weight-bearing exercises, stretching exercises, and bilateral-arm and inter-arm coordination exercises. The program will be administered in three 60-minute sessions/week over three consecutive months by three pediatric rehabilitation specialists.
Category
Rehabilitation

2

Description
Intervention group: 1) Children will receive three 15-minute reciprocal electrical stimulation per week for three successive months. A computerized electrical stimulator (Vectra®2C; Chattanooga, TS, USA) with a dual-channel stimulating unit will be used, each channel has two small-size, rectangular carbon rubber electrodes (3x5 cm), which will be enclosed in two spongy covers. Channel 1 will be applied to wrist and finger flexors while channel 2 will be applied to wrist and finger extensors. Simulation parameters will be: symmetrical biphasic square waveform, frequency of 30 Hz, a pulse width of 300 µs, the up- and down-ramp times will be set on an individual basis to avoid the stretch-reflex from becoming elicited, alternating cyclic time (wrist 5 seconds for flexors and 10 seconds for extensors), the intensity will be adjusted to the sensory threshold to acclimate the children to the stimulation and will then be increased until visible contraction will be achieved. 2) children will receive a physical rehabilitation program emphasizing functional strength training, hand weight-bearing exercises, stretching exercises, and bilateral-arm and inter-arm coordination exercises. The program will be administered in three 60-minute sessions/week over three consecutive months by three pediatric rehabilitation specialists.
Category
Rehabilitation

3

Description
Intervention group: 1) Will receive a single set of intramuscular injection of botulinum toxin-A (Botox®, Allergan PLC, Dublin, Ireland). To increase injection tolerance, children will be sedated using oral midazolam (0.5 mg/kg). The dosage will be 0.5-2 U kg-1/muscle group, with a total dosage of 12 U kg-1 (and will never exceed a maximum total dose of 400 U). An ultrasound-guided injection procedure will be used to determine the locations of injection. 2) Children will receive three 15-minute reciprocal electrical stimulation per week for three successive months. A computerized electrical stimulator (Vectra®2C; Chattanooga, TS, USA) with a dual-channel stimulating unit will be used, each channel has two small-size, rectangular carbon rubber electrodes (3x5 cm), which will be enclosed in two spongy covers. Channel 1 will be applied to wrist and finger flexors while channel 2 will be applied to wrist and finger extensors. Simulation parameters will be: symmetrical biphasic square waveform, frequency of 30 Hz, a pulse width of 300 µs, the up- and down-ramp times will be set on an individual basis to avoid the stretch-reflex from becoming elicited, alternating cyclic time (wrist 5 seconds for flexors and 10 seconds for extensors), the intensity will be adjusted to the sensory threshold to acclimate the children to the stimulation and will then be increased until visible contraction will be achieved. 3) children will receive a physical rehabilitation program emphasizing functional strength training, hand weight-bearing exercises, stretching exercises, and bilateral-arm and inter-arm coordination exercises. The program will be administered in three 60-minute sessions/week over three consecutive months by three pediatric rehabilitation specialists.
Category
Rehabilitation

4

Description
Intervention group: 1) children will receive a physical rehabilitation program emphasizing functional strength training, hand weight-bearing exercises, stretching exercises, and bilateral-arm and inter-arm coordination exercises. The program will be administered in three 60-minute sessions/week over three consecutive months by three pediatric rehabilitation specialists
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center

Physical Therapy Outpatient Clinic, Prince Sattam bin Abdulaziz University

Full name of responsible person
Ragab Kamal Elnaggar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Prince Sattam bin Abdulaziz University/Deanship of Scientific Research

Full name of responsible person
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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
Prince Sattam bin Abdulaziz University/Deanship of Scientific Research

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
Prince Sattam bin Abdulaziz University

Full name of responsible person
Ragab Kamal Elnaggar

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable