

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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

Country

Egypt

Phone

+20 2 33954577

Email address

rke_pt2001@yahoo.com

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 randomly 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

Street address

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Phone

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Email

r.elnaggar@psau.edu.sa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Prince Sattam bin Abdulaziz University/Deanship of Scientific Research

Full name of responsible person

Ragab Kamal Elnaggar

Street address

Sa'ad Ibn Mu'adh

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Al-Kharj

Postal code

16278

Phone

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Email

r.elnaggar@psau.edu.sa

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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Contact

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Prince Sattam bin Abdulaziz University

Full name of responsible person

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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