

Single blinded cross over trial of two, versus multiple, injections of Botulinum A (Dysport), into the gastrocnemius muscle of children with cerebral palsy, to compare efficacy and discomfort of either method.

Submission date 30/09/2004	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/07/2009	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0171133935

Study information

Scientific Title

Study objectives

How can injection technique be improved to increase efficacy per dose of botulinum toxin, as measured by observational gait analysis.

This study will examine whether multiple injection technique treatment is more effective than single injection technique, for spastic muscle in children with cerebral palsy. We shall examine the effect of dividing the standard treatment of single injections of Botulinum to the Gastrocnemius muscle into multiple smaller injections.

We shall also compare discomfort at time of injection, by standardised child and parent reporting scales.

Null hypothesis - there is no difference in efficacy or adverse effects between single versus multiple injections.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Nervous System Diseases: Cerebral palsy

Interventions

Randomised Controlled Trial.

Children are recruited to the study and consent is signed by themselves and/or their carers. They are randomised to group A or group B.

Group A:

Proceed first to single injections to the gastrocnemius 2 cm each side of the midline, one fifth of the distance from the tibial condyles to the ankle malleoli. A total dose of Botulinum A (Dysport) of 12 Units/kg, to a maximum 500 Units, is given in two divided fractions, using a concentration of Botulinum A (Dysport) 500 Units in 5 ml N saline.

Six months later they receive the same total dose of Botulinum A at the same concentration but divided into 10 fractions. Five injections are given 2 cm on either side of the midline of the muscle and evenly spaced, starting one fifth of the distance from the tibial condyles to the ankle malleoli and ending just past the major bulge of the gastrocnemius muscle.

Group B:

First receive the multiple injections, then six months later single injections using the same techniques as for Group A.

For each injection, the injected area of skin is treated with local anaesthetic gel (Amethocaine), 1 hour beforehand. Thirty minutes before injection, they are given oral midazolam 0.7 mg/kg as relaxant, and oral diclofenac 1 mg/kg as analgesic.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Botulinum A (Dysport)

Primary outcome measure

1. Efficacy of Botulinum toxin injection to that muscle, as assessed by observational gait scale, before at 4 weeks and at 12 weeks
2. The discomfort at the time of injection

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2003

Completion date

01/12/2005

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

20, 4-12 year old children. Boys and girls with cerebral palsy (hemiplegia and diplegia)

Participant type(s)

Patient

Age group

Child

Lower age limit

4 Years

Upper age limit

12 Years

Sex

Not Specified

Target number of participants

20

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/12/2003

Date of final enrolment

01/12/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

c/o Derby Children's Hospital

Derby

United Kingdom

DE22 3NE

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)**Funder type**

Other

Funder Name

Nottingham Primary Care Research Partnership (UK)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration