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 | Recruitment status | Prospectively registered |
|-------------------|-------------------------|--|
| 30/09/2004 | Stopped | ☐ Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 30/09/2004 | Stopped | Results |
| Last Edited | Condition category | Individual participant data |
| 23/07/2009 | Nervous System Diseases | ☐ Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

- 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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 years

Upper age limit

12 years

Sex

Not Specified

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

United Kingdom

England

Study participating centre c/o Derby Children's Hospital

Derby United Kingdom DE22 3NE

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Other

Funder Name

Nottingham Primary Care Research Partnership (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration