ISRCTN24558210 https://doi.org/10.1186/ISRCTN24558210

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr R Morton

Contact details
c/o Derby Children's Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE
+44 (0)1332 340131
richard.morton@derbyhospitals.nhs.uk

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