ISRCTN37525568 https://doi.org/10.1186/ISRCTN37525568

Comparison of low dose versus high dose Botulinum toxin (Dysport) in the treatment of children with hemiplegic cerebral palsy.

Submission date 23/01/2004	**Recruitment status** No longer recruiting
Registration date 23/01/2004	**Overall study status** Completed
Last Edited 22/02/2008	**Condition category** Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Chris Ward

Contact details
Southern Derbyshire Acute Hospitals NHS Trust
Derby City General Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE
+44 (0)1332 340141 Ext 5680
c.d.ward@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RBF 96X23

Study information

Scientific Title

Study objectives
Is 24 ng Dysport/Kg body weight more efficacious than 8 ng Dysport/Kg (using impairment measures)

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
1. 24 ng Dysport/kg body weight
2. 8 ng Dysport/kg (using impairment measures)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Botulinum toxin (Dysport)

Primary outcome measure
1. Impairment measure using gait analysis
2. Gastrocnemius muscle length was calculated at each visit using the method described by Eames and used as primary outcome measure

Secondary outcome measures
Secondary outcome variable was maximum ankle angle measured during stance and swing phases.

Overall study start date
01/03/1997

Completion date
31/07/2000

Eligibility

Key inclusion criteria
Children with hemiplegic cerebral palsy

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/1997

Date of final enrolment
31/07/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southern Derbyshire Acute Hospitals NHS Trust
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Trent (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/08/2002		Yes	No