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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
Secondary outcome variable was maximum ankle angle measured during stance and swing phases.

Completion date
31/07/2000

Eligibility

Key inclusion criteria
Children with hemiplegic cerebral palsy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

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
United Kingdom

England

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)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Trent (UK)

Results and Publications

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