

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	☐ Prospectively registered
Registration date 23/01/2004	Overall study status Completed	☐ Protocol
Last Edited 22/02/2008	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☒ 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

Primary study design

Interventional

Study design

Randomised controlled trial

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