

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/02/2008	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# 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  
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DE22 3NE

## **Sponsor information**

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

**Sponsor details**  
The Department of Health  
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79 Whitehall  
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**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?
<a href="#">Results article</a>	Results	01/08/2002		Yes	No