Botulinum Toxin in the management of spasticity in children with cerebral palsy: a randomised double blind trial

Submission date 23/01/2004	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 23/01/2004	Overall study status Completed	 Statistical analysis plan Results
Last Edited 29/11/2013	Condition category Nervous System Diseases	 Individual participant data Record updated in last year

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 BIO057 RSU/441418

Study information

Scientific Title

Study objectives Not provided at time of registration

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) Not Specified

Participant information sheet

Health condition(s) or problem(s) studied Cerebral palsy

Interventions Botulinum toxin vs placebo

Intervention Type Other

Phase Not Specified

Primary outcome measure Not provided at time of registration

Secondary outcome measures Not provided at time of registration Overall study start date 10/01/2000

Completion date 31/01/2003

Eligibility

Key inclusion criteria Children with spastic diplegia or hemiplegia

Participant type(s) Patient

Age group Child

Sex Not Specified

Target number of participants Not provided at time of registration

Key exclusion criteria Not provided at time of registration

Date of first enrolment 10/01/2000

Date of final enrolment 31/01/2003

Locations

Countries of recruitment England

United Kingdom

Study participating centre St James' University Hospital Leeds United Kingdom LS9 7TF

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 Northern and Yorkshire (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