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

Recruitment status	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Nervous System Diseases	Record updated in last year
	Overall study status Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Socrates Roussounis

Contact details

St James' University Hospital Yorkshire Regional Child Development Centre Beckett Street Leeds United Kingdom LS9 7TF +44 0113 206 5846

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