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A prospective randomised double blind study of dosage efficacy of Botox® Vs Dysport® in children with spastic diplegic cerebral palsy (CP)

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
02/05/2018

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number
N0123134254

Study information

Scientific Title

A prospective randomised double blind study of dosage efficacy of Botox® Vs Dysport® in children with spastic diplegic cerebral palsy (CP)

Study objectives
To determine the efficacy ratio of Botox® and Dysport® in spastic cerebral palsy for comparable outcomes.

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
Cerebral palsy

Interventions
Randomised controlled trial to determine the dosage efficacy of Botox versus Dysport in spastic cerebral palsy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Botulinum toxin type A (Botox®, Dysport®)

Primary outcome(s)
Functional improvement at 12 months, need for further injections

Key secondary outcome(s)
Not provided at time of registration

Completion date
06/06/2004

Eligibility

Key inclusion criteria

Spastic diplegic symmetrical CP children with >2 + equinus deformity or tight hamstrings

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
17/12/2003

Date of final enrolment
06/06/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester
Leicester
United Kingdom
LE1 4PW

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospitals of Leicester NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration