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Botulinum toxin: an adjunct in limb reconstruction - Can it reduce pain and joint complications in the lengthening phase?

Submission date 18/02/2008	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/02/2008	**Overall study status** Stopped	
Last Edited 30/01/2020	**Condition category** Surgery	

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
NCT00624299

Secondary identifying numbers
SCH-07-006; Sponsor ref: 7860

Study information

Scientific Title
Botulinum toxin: an adjunct in limb reconstruction - Can it reduce pain and joint complications in the lengthening phase?

Acronym
Botox

Study objectives
The surgery to correct leg and foot deformities in children is a lengthy, and sometimes, difficult procedure. Metal frames are attached to the leg and/or foot and over a period of time the frame is manipulated to obtain the corrected position. During this period the muscles and skin become very tight which causes pain and may pull the joint out of position. When this happens it is sometimes necessary to stop the treatment before the best position is obtained. This means that not only is the child left with an inadequate result but that further surgery is required in the future. If the tension could be removed whilst the treatment is underway this would reduce the pain, the possibility of joint damage and potentially allow a more satisfactory to be obtained without the need for further surgery.

Botulinum toxin or Botox®, as it is commonly called, has the potential to temporarily reduce the tension in the muscles without causing permanent damage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
An application has been submitted to the North Sheffield Research Ethics Office. Approval pending as of 18/02/2008.

Study design
Patient/assessor-blinded, pilot, 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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Limb reconstruction surgery

Interventions
Patients and the researcher collecting data will be blinded to the allocation of treatment.

Intervention group: Botulinum toxin intramuscular injections, 4 units per kg body weight
Control group: Saline injections

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Botulinum toxin (Botox®)

Primary outcome measure
Pain levels using a visual analogue scale validated at the Sheffield Children's Hospital. Following discharge from hospital, patients will be asked to continue recording pain level three times a day for 18 month or until discharged i.e. end of episode, which ever is first.

Secondary outcome measures
1. Range of movement in affected joints measured by a goniometre, recorded at each clinic visit until one month from the end of lengthening
2. Walking measured using a pedometer, recorded at each clinic visit until one month from the end of lengthening
3. Scores of the Child Health Questionnaire and the Pediatric Outcome Data Collection Instrument, administered pre-operatively, one month post-lengthening completion and one year from surgery

Overall study start date
01/04/2008

Completion date
01/04/2010

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Any child having reconstruction surgery which involves the distraction of bone and or soft tissue for femoral or tibial deformity and congenital talipes equinovarus.
2. Children between the ages of 6 and 18 years attending the Sheffield Children's NHS Trust

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
36

Key exclusion criteria
Children with neurological aetiology

Date of first enrolment
01/04/2008

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Children's Hospital
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
Sheffield Children's NHS Foundation Trust (UK)

Sponsor details
c/o Mrs Vee Mapunde
Clinical Research Facility
D Floor Stephenson Wing
Western Bank
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England
United Kingdom
S10 2TH

+44 (0)114 2267846
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Sponsor type
Hospital/treatment centre

Website
http://www.sheffieldchildrenscrf.nhs.uk

ROR
https://ror.org/02md8hv62

Funder(s)

Funder type
Charity

Funder Name
Sheffield Hospitals NHS Charitable Trust (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