

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/02/2008	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/01/2020	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

ClinicalTrials.gov (NCT)
NCT00624299

Protocol serial number
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 result 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.

Primary study design

Interventional

Study design

Patient/assessor-blinded, pilot, randomised controlled trial.

Study type(s)

Treatment

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(s)

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 months or until discharged i.e. end of episode, whichever is first.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

United Kingdom

England

Study participating centre

Sheffield Children's Hospital

Sheffield

United Kingdom

S10 2TH

Sponsor information

Organisation

Sheffield Children's NHS Foundation Trust (UK)

ROR

<https://ror.org/02md8hv62>

Funder(s)

Funder type

Charity

Funder Name

Sheffield Hospitals NHS Charitable Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration