Clinical trial results:
Botulinum Toxin: an adjunct in limb reconstruction – can it reduce pain and joint complications in the lengthening phase?

Summary

EudraCT number	2008-000853-37
Trial protocol	GB
Global end of trial date	09 June 2009

Results information

Result version number	v1 (current)
This version publication date	21 December 2019
First version publication date	21 December 2019
Summary attachment (see zip file)	study summary (summary.docx) declaration of end of trial form (Declaration_Of_The_End_Of_Trial.doc) end of study declaration. Annex 1 (End of Study Declaration annex 1.doc)

Trial information

Trial identification

Sponsor protocol code	SCH/07/006

Additional study identifiers

ISRCTN number	ISRCTN35609758
ClinicalTrials.gov id (NCT number)	NCT00624299
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sheffield Childrens Hospital NHS Foundation Trust
Sponsor organisation address	Western Bank, Sheffield, United Kingdom, S10 2TH
Public contact	Dominic Nash R&D Manager Sheffield Childrens Hospital NHS Foundation Trust, Sheffield Childrens Hospital NHS Foundation Trust, 44 01143053478, dominic.nash@nhs.net
Scientific contact	Dominic Nash R&D Manager Sheffield Childrens Hospital NHS Foundation Trust, Sheffield Childrens Hospital NHS Foundation Trust, 44 01143053478, dominic.nash@nhs.net

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No	No

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	09 June 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 June 2009
Global end of trial reached?	Yes
Global end of trial date	09 June 2009
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Does the injection of a single dose of Botulinum toxin reduce pain, protect the stability of the joint and improve function in children who have limb reconstruction surgery (LRS)?

Protection of trial subjects:

NA

Background therapy:

Saline is injected into the muscles known to cause problems

Evidence for comparator:

In children undergoing limb reconstruction surgery it is thought that an injection of Botulinum toxin into key muscles reduce pain, maintain the range of motion in the knee and / or ankle joint and enhance their independence and quality of life

Actual start date of recruitment	31 March 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 2
Worldwide total number of subjects	2
EEA total number of subjects	2

Notes:

Subjects enrolled per age group

In utero	2
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Scientific peer review of the protocol raised ethical issues on the basis that a larger, similar study was being conducted in Canada and on this basis it was recommended that the study does not receive additional funding. Following this advice the decision was taken not to proceed with the trial. No participants have been recruited

Pre-assignment

Screening details:

Scientific peer review of the protocol raised ethical issues on the basis that a larger, similar study was being conducted in Canada and on this basis it was recommended that the study does not receive additional funding. Following this advice the decision was taken not to proceed with the trial. No participants have been screened

Period 1

Period 1 title	09/06/2009 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind[1]
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

The child, parents, and researcher will be blind to the group allocation only the surgeon will know which child receives the drug. (The preferred method of randomisation would have allowed the surgeon to be blinded too but the logistics of the drug being prepared in pharmacy made it impossible to achieve).

Arms

Are arms mutually exclusive?	Yes
Arm title	Botox

Arm description:

Botox injection

Arm type	Active comparator
Investigational medicinal product name	Botulinum Toxin
Investigational medicinal product code	
Other name	Botox
Pharmaceutical forms	Injection
Routes of administration	Intramuscular and intravenous use

Dosage and administration details:

4-6 units per kilo of body weight

Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular and intravenous use

Dosage and administration details:

is 4-6 units per kilo of body weight

Arm title	Placebo

Arm description:

Saline injection is given as a placebo

Arm type	Placebo

Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular and intravenous use

Dosage and administration details:

4-6 units per kilo of body weight

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.
Justification: Following scientific peer review of the protocol the feedback received raised ethical issues on the basis that a larger, similar study was being conducted in Canada and on this basis it was recommended that the study does not receive additional funding. Following this advice the decision was taken not to proceed with the trial. No participants have been recruited therefore there are no adverse implications for this decision.

Number of subjects in period 1	Botox	Placebo
Started	1	1
Completed	1	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Botox
Reporting group description: Botox injection	
Reporting group title	Placebo
Reporting group description: Saline injection is given as a placebo	

Primary: pain reduction in knee and ankle joint

End point title	pain reduction in knee and ankle joint[1]

End point description:

In children undergoing limb reconstruction surgery will the injection of Botulinum toxin into key muscles reduce the pain, maintain the range of motion in the knee and / or ankle joint and enhance their independence and quality of life?

End point type	Primary

End point timeframe:

End of study

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Following scientific peer review of the protocol the feedback received raised ethical issues on the basis that a larger, similar study was being conducted in Canada and on this basis it was recommended that the study does not receive additional funding. Following this advice the decision was taken not to proceed with the trial. No participants have been recruited therefore there are no adverse implications for this decision.

End point values	Botox	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: NA				

Notes:

[2] - Following peer review advice the decision was taken not to proceed with the trial

[3] - Following peer review advice the decision was taken not to proceed with the trial

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Following peer review advice the decision was taken not to proceed with the trial. No participants have been recruited therefore there are no adverse events arose

Assessment type	Systematic

Dictionary used

Dictionary name	EDMS
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Following scientific peer review of the protocol the feedback received raised ethical issues on the basis that a larger, similar study was being conducted in Canada and on this basis it was recommended that the study does not receive additional funding. Following this advice the decision was taken not to proceed with the trial. No participants have been recruited therefore there are no adverse implications for this decision.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported