Clinical trial results:
Botulinum toxin type A block of the otic ganglion in chronic cluster headache. Safety issues.

Summary

EudraCT number	2016-004213-28
Trial protocol	NO
Global end of trial date	31 May 2019

Results information

Result version number	v1 (current)
This version publication date	29 July 2021
First version publication date	29 July 2021
Summary attachment (see zip file)	Published paper (Crespi Otic Ganglion SPG.pdf)

Trial information

Trial identification

Sponsor protocol code	OTOBLOCKCH2016

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03066635
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	NTNU
Sponsor organisation address	Edvard Griegs gt 8, Trondheim, Norway, 7030
Public contact	Lars Jacob Stovner, Department of Neuroscience, NTNU, 0047 72575070, erling.tronvik@ntnu.no
Scientific contact	Lars Jacob Stovner, Department of Neuroscience, NTNU, +47 40458528, erling.tronvik@ntnu.no

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 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 May 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 May 2019
Global end of trial reached?	Yes
Global end of trial date	31 May 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate safety

Protection of trial subjects:

All participants were given extensive information prior to participation on the experimental nature of this pilot trial and potential risks.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 2017
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	Norway: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

Notes:

Subjects enrolled per age group

In utero	0
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)	9
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruited from the out patient clinic, St. Olavs Hospital Trondheim from June 2017 to May 2019

Pre-assignment

Screening details:

11 patients were screened, one was screening failure due to too few headache attacks in the baseline period.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Treatment

Arm description: -

Arm type	Experimental
Investigational medicinal product name	botulinum toxin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

12,5 Allergan units Botox injected in 5 patients and 25 units Botox injected in 5 patients

Number of subjects in period 1	Treatment
Started	10
Completed	10

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	10	10	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	55		
standard deviation	± 12	-	
Gender categorical Units: Subjects			
Female	5	5	
Male	5	5	

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description: -

Primary: Safety

End point title	Safety[1]

End point description:

End point type	Primary

End point timeframe:

June 2017 - May 2019

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: The primary objective of this pilot trial in 10 patients was to evaluate safety. All safety data were given in full and no statistical analyses were performed on this parameter.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Occurrence of adverse events				
number (not applicable)	10			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: June 2017 - May 2019	
Assessment type	Systematic
Dictionary used	
Dictionary name	WebCRF - NTNU
Dictionary version	2.0
Reporting groups	
Reporting group title	Treatment

Reporting group description: -

Serious adverse events	Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 10 (60.00%)		
Injury, poisoning and procedural complications			
Transient pain or swelling at site of injection			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		
Transient jaw stiffness or discomfort gaping at injection site			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Nervous system disorders			
Transient chin numbness			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Transient discomfort swallowing			

subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Transient articulation difficulties due to local discomfort			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Transient nasal voice			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Transient hyperacusis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Transient tinnitus			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Transient ear fullness			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Endocrine disorders			
Transient dry mouth			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This was a small pilot trial in only 10 patients to evaluate safety of the intervention.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32583902