Clinical trial results:
Endoscopic block of the sphenopalatine ganglion with botulinum toxin in intractable cluster headache. Safety issues.

Summary

EudraCT number	2012-000248-91
Trial protocol	NO
Global end of trial date	09 September 2014

Results information

Result version number	v1 (current)
This version publication date	03 September 2021
First version publication date	03 September 2021

Trial information

Trial identification

Sponsor protocol code	BTACH2012

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	NTNU
Sponsor organisation address	Edvard Griegs Gate 8, Trondheim, Norway, 7030
Public contact	Lars Jacob Stovner, Institutt for nevromedisin, NTNU, 0047 NA72575070NA, lars.stovner@ntnu.no
Scientific contact	Lars Jacob Stovner, Institutt for nevromedisin, NTNU, 0047 NA72575070NA, lars.stovner@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	01 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 June 2014
Global end of trial reached?	Yes
Global end of trial date	09 September 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety of injections of botulinum toxin towards the sphenopalatine ganglion in cluster headache

Protection of trial subjects:

- Respect: All patients were treated with respected
- Beneficence: Care taken to protect participants from inadvertent risk
- The trial was reviewed by IRB
- The trial was monitored by Data Safety Monitoring Board

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Ten patients with intractable chronic CH were recruited from the Neurology Department and by referrals from collaborating headache experts within Norway.

Period 1

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

Blinding implementation details:

None

Arms

Arm title	Treatment

Arm description: -

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

Dosage and administration details:

The first five patients received 25 IU BTA, the last five received 50 IU.

Number of subjects in period 1	Treatment
Started	10
Completed	7
Not completed	3
Lost to follow-up	3

Baseline characteristics

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description: -

Primary: Adverse events

End point title	Adverse events[1]

End point description:

End point type	Primary

End point timeframe:

Assessed through tabulation from the treatment procedure to the end of the 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: Data on adverse event where provided in full in this single arm no blinded pilot study and no statistical analyses were performed on this parameter.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Number of adverse events	11			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: During the whole study post treatment	
Assessment type	Systematic

Dictionary used	
Dictionary name	NTNU WEB CRF
Dictionary version	3.0

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Blood and lymphatic system disorders			
Posterior epistaxis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 10 (70.00%)		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Attack related weakness one foot			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Blood and lymphatic system disorders			

Anterior epistaxis subjects affected / exposed occurrences (all)	3 / 10 (30.00%) 3		
Eye disorders Accommodation disorder subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2		
Musculoskeletal and connective tissue disorders Jaw problems subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		

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