



## Clinical trial results:

### Botulinum toxin type A block of the sphenopalatine ganglion in chronic migraine. Safety issues

#### Summary

EudraCT number	2014-001852-43
Trial protocol	NO
Global end of trial date	01 February 2016

#### 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	BTACM2014
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02259075
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, Department of Neuroscience, NTNU, lars.stovner@ntnu.no
Scientific contact	Lars Jacob Stovner, Department of Neuroscience, NTNU, 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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	02 May 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 February 2016
Global end of trial reached?	Yes
Global end of trial date	01 February 2016
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

Main objective of the trial:

To evaluate the safety

Protection of trial subjects:

- Respect: All patients were treated with respect
- 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 September 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**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:

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**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: -

### Pre-assignment

Screening details:

Ten patients with chronic migraine 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:

Aided by surgical navigation and MultiGuide, BTA was injected towards the SPG. All patients received 25 IU BTA suspended in 0.5 ml isotonic saline on each side for a total dose of 50 IU

Number of subjects in period 1	Treatment
Started	10
Completed	9
Not completed	1
Protocol deviation	1

## Baseline characteristics

## End points

### End points reporting groups

Reporting group title	Treatment
Reporting group description: -	

### Primary: Adverse events

End point title	Adverse events <sup>[1]</sup>
End point description:	

End point type	Primary
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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.

<b>End point values</b>	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Number of adverse events	25			

### 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
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### Dictionary used

Dictionary name	NTNU WEB CRF
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Dictionary version	3.0
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### Reporting groups

Reporting group title	Overall trial
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Reporting group description: -

Serious adverse events	Overall trial		
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	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)		
Surgical and medical procedures			
Pain,swelling and numbness			
subjects affected / exposed	10 / 10 (100.00%)		
occurrences (all)	8		
Jaw problems			
subjects affected / exposed	7 / 10 (70.00%)		
occurrences (all)	7		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Eye disorders			

Tearing subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Visual disturbances subjects affected / exposed occurrences (all)	3 / 10 (30.00%) 3		
Dry eye subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Gastrointestinal disorders Dysphagia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Nausea subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Respiratory, thoracic and mediastinal disorders Nasal obstruction subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1		
Musculoskeletal and connective tissue disorders Temporomandibular joint dysfunction 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

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported