Clinical trial results:
Botulinum neurotoxin type A treatment for sialorrhea in central nervous system diseases

Summary

EudraCT number	2015-000682-30
Trial protocol	EE
Global end of trial date	12 November 2018

Results information

Result version number	v1 (current)
This version publication date	07 April 2022
First version publication date	07 April 2022
Summary attachment (see zip file)	Does Botulinum neurotoxin type A treatment for sialorrhea 2017 (Does Botulinum neurotoxin type A treatment for sialorrhea 2017.pdf) Saliva changes in Parkinson's disease patients 2018 (Saliva changes in Parkinson's disease patients 2018.pdf) Use of botulinum neurotoxin A 2012 (Use of botulinum neurotoxin A 2012.pdf)

Trial information

Trial identification

Sponsor protocol code	01-09.02.15.

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Tartu University Hospital
Sponsor organisation address	Puusepa 1A, Tartu, Estonia, 50406
Public contact	Tartu University Hospital Clinic , Tartu University Hospital Clinic , janne.tiigimae-saar@kliinikum.ee
Scientific contact	Tartu University Hospital Clinic , Tartu University Hospital Clinic , janne.tiigimae-saar@kliinikum.ee

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	12 November 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 November 2018
Global end of trial reached?	Yes
Global end of trial date	12 November 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1.Evaluate and compare salivary compositions and microflora change after BNT-A injections describing the status of caries and periodontal health.
2. Evaluate the BNT-A efficiency in treatment of average and hard sialorrhea patients.
3. Evaluate the BNT-A effect on patients life-quality.

Protection of trial subjects:

Ethics commitee approval obtained. Informed consent obtained.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 March 2015
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	Estonia: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	12
Adolescents (12-17 years)	0
Adults (18-64 years)	25
From 65 to 84 years	43
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Totally 67 patients were enrolled to the study group. In the control group there were 13 patients

Pre-assignment

Screening details:

Informed consent from the patient and/or caregiver was needed.

Period 1

Period 1 title	Study group (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Experimental
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Botulinum neurotoxin type A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intraglandular use
Dosage and administration details: 250 units	
Arm title	Control group
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Experimental	Control group
Started	67	13
Completed	67	13

Baseline characteristics

Reporting groups

Reporting group title	Study group

Reporting group description: -

Reporting group values	Study group	Total	
Number of subjects	80	80	
Age categorical Units: Subjects			
Children (2-11 years)	14	14	
Adults (18-64 years)	23	23	
From 65-84 years	43	43	
Gender categorical Units: Subjects			
Female	36	36	
Male	44	44	

Subject analysis sets

Subject analysis set title	Per protocol
Subject analysis set type	Per protocol

Subject analysis set description:

Subject analysis set is described in the articles

Reporting group values	Per protocol		
Number of subjects	80		
Age categorical Units: Subjects			
Children (2-11 years)	14		
Adults (18-64 years)	23		
From 65-84 years	43		
Gender categorical Units: Subjects			
Female	44		
Male	36		

End points

End points reporting groups	
Reporting group title	Experimental
Reporting group description: -	
Reporting group title	Control group
Reporting group description: -	
Subject analysis set title	Per protocol
Subject analysis set type	Per protocol
Subject analysis set description: Subject analysis set is described in the articles	

Primary: Salivary flow rate	
End point title	Salivary flow rate
End point description:	
End point type	Primary
End point timeframe: Resting saliva time, seconds	

End point values	Experimental	Control group	Per protocol	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	67	13	13	
Units: second	67	13	13	

Statistical analyses

Statistical analysis title	Study result analysis
Comparison groups	Experimental v Control group
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 1-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Starting from study medication injection	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	21
Reporting groups	
Reporting group title	All study subjects
Reporting group description:	
All study subjects	

Serious adverse events	All study subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 67 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	All study subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 67 (1.49%)		
Gastrointestinal disorders			
Difficulties with swallowing			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 67 (1.49%)		
occurrences (all)	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