

**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.
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**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 committee 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
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<b>Arm title</b>	Experimental
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Arm description: -

Arm type	Experimental
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Investigational medicinal product name	Botulinum neurotoxin type A
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Suspension for injection
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Routes of administration	Intraglandular use
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Dosage and administration details:

250 units

<b>Arm title</b>	Control group
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Arm description: -

Arm type	No intervention
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No investigational medicinal product assigned in this arm

<b>Number of subjects in period 1</b>	Experimental	Control group
Started	67	13
Completed	67	13

## Baseline characteristics

### Reporting groups

Reporting group title	Study group
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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
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Subject analysis set type	Per protocol
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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

<b>Serious adverse events</b>	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 %

<b>Non-serious adverse events</b>	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

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported