



Clinical trial results: Intragastrale Injektion von Botulinum Toxin A zur Behandlung der Adipositas

Summary

EudraCT number	2005-001095-13
Trial protocol	AT
Global end of trial date	31 March 2017

Results information

Result version number	v1 (current)
This version publication date	12 February 2022
First version publication date	12 February 2022

Trial information

Trial identification

Sponsor protocol code	99999
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52, Innsbruck, Austria, 6020
Public contact	Prim. Univ.-Prof. Dr. Reinhard Mittermair, Klinikum Klagenfurt, Abteilung für Allgemein- und Viszeralchirurgie, Feschnigstrasse 11, 9020 K, +43 (0)46353831403, Reinhard.Mittermair@kabeg.at
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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	29 December 2006
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 December 2006
Global end of trial reached?	Yes
Global end of trial date	31 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Hypothetically, BTX-A should inhibit the acetylcholine-mediated peristalsis, which is mainly responsible for gastric motility, and thereby induce slowed gastric emptying, earlier satiety and weight loss. The aim of this study was to observe the effects of endoscopic intragastric injections of BTX-A in obese patients.

Protection of trial subjects:

Subjects received standard of care treatment depending on their medical history.

Background therapy:

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Evidence for comparator:

Subjects with class I obesity (body mass index 30-35) were double-blind randomized into 2 groups (BTX-A and 0.9% Saline).

Actual start date of recruitment	13 June 2005
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	Austria: 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
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Subject disposition

Recruitment

Recruitment details:

Healthy adult subjects with class I obesity, i.e. body mass index (BMI) 30-35 kg/m², were screened.

Pre-assignment

Screening details:

All patients agreed not to undergo any weight loss treatment during the study.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Patients with class I obesity (body mass index 30-35) were double-blind randomized into 2 groups (BTX-A and 0.9% Saline).

Arms

Are arms mutually exclusive?	Yes
Arm title	BTX-A

Arm description:

Group 1 (BTX-A): endoscopic injection of 200U BTX-A into the antrum and distal gastric body. Body weight and height were measured, and BMI was calculated immediately before the endoscopic injection. After treatment, weight and BMI were determined monthly until the end of the study (6 months).

Arm type	Experimental
Investigational medicinal product name	Botox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Gastroenteral use

Dosage and administration details:

BTX-A (Botox ®, Allergan, Irvine, CA, USA) – with 100 U of botulinum toxin A – was reconstituted in 0.9% sodium chloride. Two BTX-A were used and each reconstituted in 8 ml 0.9% sodium chloride (200 U BTX-A in 16 ml diluent). The volume of the diluent used corresponded to the number of puncture sites (16 times). Thus, 1 ml of BTX-A solution was injected at each puncture site. Puncture of the gastric wall was performed in a circular manner, with four punctures in each of four circles: The four circles were located 4, 6, 8 and 12 cm cranial to the pylorus. BTX-A was injected into the gastric wall using a standard 5-mm protruding sclerotherapy needle. The sclerotherapy needle was introduced deeply into the gastric wall, and the BTX-A solution was slowly injected. At the last puncture site, saline was injected through the needle to push out the BTX-A solution remaining in the lumen.

Arm title	Control
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Arm description:

Group 2 (control): endoscopic injection of 0.9% sodium chloride into the antrum and distal gastric body. Body weight and height were measured, and BMI was calculated immediately before the endoscopic injection. After treatment, weight and BMI were determined monthly until the end of the study (6 months).

Arm type	Placebo
Investigational medicinal product name	0.9% Sodium Chloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Gastroenteral use

Dosage and administration details:

The volume of the solution (16 mL 0.9% sodium chloride) corresponded to the number of puncture sites (16 times). Thus, 1 ml of 0.9% sodium chloride solution was injected at each puncture site. Puncture of the gastric wall was performed in a circular manner, with four punctures in each of four circles: The four circles were located 4, 6, 8 and 12 cm cranial to the pylorus. 0.9% sodium chloride was injected into the gastric wall using a standard 5-mm protruding sclerotherapy needle. The sclerotherapy needle was introduced deeply into the gastric wall, and the 0.9% sodium chloride solution was slowly injected. At the last puncture site, saline was injected through the needle to push out the 0.9% sodium chloride solution remaining in the lumen.

Number of subjects in period 1	BTX-A	Control
Started	5	5
Completed	5	5

Baseline characteristics

Reporting groups

Reporting group title	BTX-A
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Reporting group description:

Group 1 (BTX-A): endoscopic injection of 200U BTX-A into the antrum and distal gastric body. Body weight and height were measured, and BMI was calculated immediately before the endoscopic injection. After treatment, weight and BMI were determined monthly until the end of the study (6 months).

Reporting group title	Control
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Reporting group description:

Group 2 (control): endoscopic injection of 0.9% sodium chloride into the antrum and distal gastric body. Body weight and height were measured, and BMI was calculated immediately before the endoscopic injection. After treatment, weight and BMI were determined monthly until the end of the study (6 months).

Reporting group values	BTX-A	Control	Total
Number of subjects	5	5	10
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	5	10
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
median	31.6	28.4	
full range (min-max)	20 to 39	21 to 35	-
Gender categorical			
Units: Subjects			
Female	5	5	10
Male	0	0	0

End points

End points reporting groups

Reporting group title	BTX-A
Reporting group description:	
Group 1 (BTX-A): endoscopic injection of 200U BTX-A into the antrum and distal gastric body. Body weight and height were measured, and BMI was calculated immediately before the endoscopic injection. After treatment, weight and BMI were determined monthly until the end of the study (6 months).	
Reporting group title	Control
Reporting group description:	
Group 2 (control): endoscopic injection of 0.9% sodium chloride into the antrum and distal gastric body. Body weight and height were measured, and BMI was calculated immediately before the endoscopic injection. After treatment, weight and BMI were determined monthly until the end of the study (6 months).	

Primary: BMI

End point title	BMI
End point description:	
End point type	Primary
End point timeframe:	
Day 0- Month 6	

End point values	BTX-A	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: kg/m2				
median (full range (min-max))				
Day 0	32.4 (31.1 to 34.0)	32.6 (31.5 to 33.5)		
Month 6	32.5 (31.1 to 34.7)	32.6 (31.1 to 34.2)		

Statistical analyses

Statistical analysis title	BMI
Comparison groups	BTX-A v Control
Number of subjects included in analysis	10
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.12
Method	t-test, 2-sided

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Day 0- Month 6

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	3.0
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Reporting groups

Reporting group title	BTX-A
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Reporting group description:

Group 1 (BTX-A): endoscopic injection of 200U BTX-A into the antrum and distal gastric body. Body weight and height were measured, and BMI was calculated immediately before the endoscopic injection. After treatment, weight and BMI were determined monthly until the end of the study (6 months).

Reporting group title	Control
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Reporting group description: -

Serious adverse events	BTX-A	Control	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	BTX-A	Control	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No non-serious adverse events or serious adverse events were observed during the trial.

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/17879570>