ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 10/25/2013

ClinicalTrials.gov ID: NCT00761592

Study Identification

Unique Protocol ID:	ALLBL001
Brief Title:	Comparison of Two Botulinum Type A Products in the Treatment of Blepharospasm
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	October 2013
Overall Status:	Completed
Study Start:	July 2006
Primary Completion:	January 2008 [Actual]
Study Completion:	January 2008 [Actual]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No

Review Board:	Approval Status: Approved Approval Number: 044/06 Board Name: Rheinische Friedrich-Wilhelms-Universitat Board Affiliation: Rheinische Friedrich-Wilhelms-Universitat Phone: 0049 228873 5415 Email: ethik@uni-bonn.de
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Germany: Federal Institute for Drugs and Medical Devices

Study Description

Brief Summary:	This pilot study estimates the treatment effects of two different types of botulinum toxin type A in the treatment of Blepharospasm. Blepharospasm is characterised by excessive contraction of the muscles around the eye and can lead to repetitive blinking or sustained closure of the eyelids.
Detailed Description:	

Conditions

Conditions:	Blepharospasm
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	65 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: 1	Biological/Vaccine: Botulinum Toxin Type A 900kDa 6 to 16 injections, with maximum of 21, at a dose of ≥20U/eye (≥40U total dose) Other Names: • BOTOX®
Active Comparator: 2	Biological/Vaccine: Botulinum Toxin Type A 150kDa 6 to 16 injections, with a maximum of 21, at a dose of ≥20U/eye (≥40U total dose) Other Names: • Xeomin®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Diagnosed with benign essential blepharospasm
- Received ≥20U/eye of BOTOX® for at least one visit prior to study entry and required, in the investigators opinion, the same dose at the study injection visit.
- Combined Jankovic Rating Score of >2

Exclusion Criteria:

- Female subjects who were pregnant, breastfeeding, or who were of childbirth potential and not practicing birth control.
- Profound atrophy of the muscles in the target area(s) of injection.
- Myasthenia Gravis, Lambert-Eaton Syndrome, Amyotrophic Lateral Sclerosis or any other disease that might interfere with neuromuscular function.
- Known significantly impaired renal and/or hepatic function

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc.

Locations: Germany
Bonn, Germany

Zwickau, Germany

Wiesbaden, Germany

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Botulinum Toxin Type A 900kDa	
Botulinum Toxin Type A 150kDa	

Overall Study

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
Started	32	33
Completed	31	32
Not Completed	1	1

Baseline Characteristics

Reporting Groups

	Description
Botulinum Toxin Type A 900kDa	
Botulinum Toxin Type A 150kDa	

Baseline Measures

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa	Total
Number of Participants	31	33	64
Age, Continuous [units: years] Mean (Standard Deviation)	70.7 (10.7)	67.1 (12.1)	68.8 (11.5)
Gender, Male/Female [1] [units: participants]			
Female	20	19	39
Male	11	14	25

[1] One patient from group 1 withdrew consent after first injection, thus efficacy data was not gathered for this patient

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in Blepharospasm Disability Index
Measure Description	Blepharospasm Disability Index is a validated 5-point scale (0-4) with six items (e.g., reading, driving a vehicle). 0 - no impairment, 1 - mild impairment, 2 - moderate impairment, 3 - severe impairment, 4 - not possible due to disease, N/A - Not applicable. The total score ranged from 0 (no impairment) to 24 (not possible due to disease). A negative change from baseline indicated improvement.
Time Frame	Baseline to Week 4
Safety Issue?	No

Analysis Population Description
Intention to Treat

Reporting Groups

	Description
Botulinum Toxin Type A 900kDa	
Botulinum Toxin Type A 150kDa	

Measured Values

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
Number of Participants Analyzed	31	33
Change From Baseline to Week 4 in Blepharospasm Disability Index [units: Points on Scale] Mean (Standard Deviation)	-2.8 (5.3)	-1.3 (3.7)

2. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in Blepharospasm Disability Index
Measure Description	Blepharospasm Disability Index is a validated 5-point (0-4) scale with six items (e.g., reading, driving a vehicle). 0 - no impairment, 1 - mild impairment, 2 - moderate impairment, 3 - severe impairment, 4 - not possible due to disease, N/A - Not applicable. The total score ranged from 0 (no impairment) to 24 (not possible due to disease). A negative change from baseline indicated improvement.
Time Frame	Baseline to Week 8
Safety Issue?	No

Analysis Population Description
Intention to Treat

Reporting Groups

	Description
Botulinum Toxin Type A 900kDa	
Botulinum Toxin Type A 150kDa	

Measured Values

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
Number of Participants Analyzed	31	33
Change From Baseline to Week 8 in Blepharospasm Disability Index [units: Points on Scale] Mean (Standard Deviation)	-1.3 (3.9)	-0.8 (3.2)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 and Week 8 in Total Jankovic Rating Scale (JRS) (Severity and Frequency Measured on a Scale of 0-4)
Measure Description	Jankovic Rating Scale Severity: 0 - None; 1 - Minimal; 2 - Mild; 3 - Moderate; 4 - Severe. Frequency: 0 - None; 1 - Slight increase; 2 - Fluttering duration less than 1 second; 3 - Spasm greater than 1 second and eyes open > 50% of waking time; 4 - Functionally blind. The range of the total score was from 0 (None) to 8 (Severe and Functionally Blind). A negative change from baseline indicated improvement.
Time Frame	Baseline to Week 4 and Week 8
Safety Issue?	No

Analysis Population Description
Intention to Treat

Reporting Groups

	Description
Botulinum Toxin Type A 900kDa	
Botulinum Toxin Type A 150kDa	

Measured Values

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
Number of Participants Analyzed	31	33
Change From Baseline to Week 4 and Week 8 in Total Jankovic Rating Scale (JRS) (Severity and Frequency Measured on a Scale of 0-4) [units: Points on Scale] Mean (Standard Deviation)		
Change in JRS in Left Eye at Week 4	-2.3 (1.5)	-1.5 (1.5)

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
Change in JRS in Right Eye at Week 4	-2.2 (1.5)	-1.5 (1.5)
Change in JRS in Left Eye at Week 8	-1.9 (1.7)	-1.3 (1.3)
Change in JRS in Right Eye at Week 8	-1.8 (1.7)	-1.3 (1.4)

4. Secondary Outcome Measure:

Measure Title	Changes From Baseline to Week 4 and Week 8 in Patient Global Assessment (PGA) Score
Measure Description	Subjective satisfaction rating: -4: marked worsening, -3: moderate worsening, -2: marked worsening in symptoms, -1: mild worsening in symptoms, 0: no effect +1: mild improvement in symptoms, +2: moderate improvement in symptoms, +3: mild improvement, +4: marked improvement. A positive change from baseline indicated improvement.
Time Frame	Baseline to Week 4 and 8
Safety Issue?	No

Analysis Population Description
Intention to Treat

Reporting Groups

	Description
Botulinum Toxin Type A 900kDa	
Botulinum Toxin Type A 150kDa	

Measured Values

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
Number of Participants Analyzed	31	33
Changes From Baseline to Week 4 and Week 8 in Patient Global Assessment (PGA) Score [units: Points on Scale] Mean (Standard Deviation)		
Change in PGA at Week 4	1.13 (1.86)	0.52 (2.14)
Change in PGA at Week 8	-0.16 (2.37)	0.19 (1.86)

5. Secondary Outcome Measure:

Measure Title	Duration of Action
Measure Description	Median Duration for decision to reinject
Time Frame	Interval between initial injection (Week 0) and final visit (Week 11 through Week 14)
Safety Issue?	No

Analysis Population Description
Intention to Treat

Reporting Groups

	Description
Botulinum Toxin Type A 900kDa	
Botulinum Toxin Type A 150kDa	

Measured Values

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
Number of Participants Analyzed	31	33
Duration of Action [units: Weeks] Median (Standard Deviation)	13.1 (2.0)	13.1 (3.0)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Botulinum Toxin Type A 900kDa	
Botulinum Toxin Type A 150kDa	

Serious Adverse Events

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/	1/
Nervous system disorders		
Carotid Artery Stenosis *	0/31 (0%)	1/33 (3.03%)
Skin and subcutaneous tissue disorders		
Angioneurotic oedema *	1/31 (3.23%)	0/33 (0%)

* Indicates events were collected by non-systematic methods.

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 1%

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
	Affected/At Risk (%)	Affected/At Risk (%)
Total	21/	24/
Eye disorders		
Diplopia *	1/31 (3.23%)	0/33 (0%)
Dry Eye *	0/31 (0%)	1/33 (3.03%)
Eye Swelling *	0/31 (0%)	1/33 (3.03%)
Eyelid oedema *	0/31 (0%)	1/33 (3.03%)
Eyelid ptosis *	4/31 (12.9%)	1/33 (3.03%)
Lacrimation increased *	1/31 (3.23%)	0/33 (0%)
Lid Lag *	0/31 (0%)	1/33 (3.03%)
Sicca Syndrome *	0/31 (0%)	2/33 (6.06%)
Gastrointestinal disorders		
Dry Mouth *	1/31 (3.23%)	0/33 (0%)
Nausea *	0/31 (0%)	1/33 (3.03%)
Salivary hypersecretion *	0/31 (0%)	1/33 (3.03%)
Infections and infestations		

	Botulinum Toxin Type A 900kDa	Botulinum Toxin Type A 150kDa
	Affected/At Risk (%)	Affected/At Risk (%)
Influenza *	0/31 (0%)	1/33 (3.03%)
Injury, poisoning and procedural complications		
Periorbital haematoma *	7/31 (22.58%)	9/33 (27.27%)
Musculoskeletal and connective tissue disorders		
Muscle Spasms *	1/31 (3.23%)	0/33 (0%)
Muscular Weakness *	1/31 (3.23%)	0/33 (0%)
Nervous system disorders		
Headache *	3/31 (9.68%)	3/33 (9.09%)
Mastication Disorder *	0/31 (0%)	1/33 (3.03%)
Paraesthesia *	0/31 (0%)	1/33 (3.03%)
Psychiatric disorders		
Nervousness *	1/31 (3.23%)	0/33 (0%)
Skin and subcutaneous tissue disorders		
Hyperhidrosis *	1/31 (3.23%)	0/33 (0%)

* Indicates events were collected by non-systematic methods.

Limitations and Caveats

This was a pilot study.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact:

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