ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 11/14/2011

ClinicalTrials.gov ID: NCT00528541

Study Identification

Unique Protocol ID:	MedAff-BTX-0616
Brief Title:	Comparison of Efficacy and Safety of Two Different Types of Botulinum Toxin Type A in Moderate to Severe Cervical Dystonia
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	November 2011
Overall Status:	Completed
Study Start:	September 2007
Primary Completion:	September 2009 [Actual]
Study Completion:	September 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 08/08/2007 Board Name: Royal Adelaide Hospital Research Ethic Committee Board Affiliation: Department of Health and Aging Therapeutic Goods Administration Phone: 61-8-8222-4139 Email: Heather.O'Dea@health.sa.gov.au
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Australia: Department of Health and Ageing Therapeutic Goods Administration

Study Description

Brief Summary:	The purpose of this study is to compare two types of botulinum toxin type A to treat the involuntary muscle contractions in the neck
Detailed Description:	

Conditions

Conditions:	Spasmodic Torticollis
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:	145 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: BOTOX® botulinum toxin type A (BOTOX®)	Biological/Vaccine: botulinum toxin type A 200 Units at Visit 1 (Day 1) Other Names: • BOTOX®
Active Comparator: Dysport® botulinum toxin type A (Dysport®)	Biological/Vaccine: botulinum toxin type A 750 Units at Visit 1 (Day 1) Other Names: • Dysport®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Diagnosed with cervical dystonia/spasmodic torticollis for at least 18 months
- Successfully treated previously with botulinum toxin type A

Exclusion Criteria:

- Breast feeding, pregnant or could become pregnant
- Surgery or spinal cord stimulation for cervical dystonia
- Previous injections of phenol, alcohol for cervical dystonia

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan

Locations: Australia, South Australia
Adelaide, South Australia, Australia

Croatia
Zagreb, Croatia

Poland
Krakow, Poland

Italy
Rome, Italy

Turkey
Istanbul, Turkey

Germany
Wurzburg, Germany

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Overall Study

	BOTOX®	Dysport®
Started	75	70

	BOTOX®	Dysport®
Completed	73	69
Not Completed	2	1

Baseline Characteristics

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Baseline Measures

	BOTOX®	Dysport®	Total
Number of Participants	75	70	145
Age, Continuous [units: years] Mean (Standard Deviation)	49.4 (12.2)	48.6 (11.5)	49.0 (11.9)
Gender, Male/Female [units: participants]			
Female	46	39	85
Male	29	31	60

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Dysphagia Incidence Over 10 Weeks
Measure Description	Dysphagia Incidence (difficulty swallowing) was defined as the number of patients reporting at least 1 treatment-emergent dysphagia event at any point in the study. Occurrences of dysphagia were captured as spontaneous events or were assessed during study visits using the Structured Symptom Interview (SSI) and the Dystonia Study Group Dysphagia Interview (DSGDI) for symptoms of difficulty swallowing; coughing while eating and drinking; choking while eating or drinking; or difficulty swallowing solids or liquids.
Time Frame	10 weeks
Safety Issue?	No

Analysis Population Description

Modified intent to treat: all patients who were randomized to treatment and received 1 dose at Visit 1.

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Measured Values

	BOTOX®	Dysport®
Number of Participants Analyzed	75	70
Dysphagia Incidence Over 10 Weeks [units: Number of patients]	10	12

2. Secondary Outcome Measure:

Measure Title	Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) Total Score at Week 4
Measure Description	The TWSTRS assessments were conducted at each study visit. The TWSTRS is an assessment scale used to measure the impact of cervical dystonia on patients. It is comprised of 3 subscales: Severity, Disability, and Pain, each of which is scored independently. The total of these 3 comprises the TWSTRS total score which is scored from 0 (least symptoms) to 85 (worst symptoms). Higher scores indicate a greater degree of symptom severity.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Modified intent to treat: all patients who were randomized to treatment and received 1 dose at Visit 1.

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Measured Values

	BOTOX®	Dysport®
Number of Participants Analyzed	75	70

	BOTOX®	Dysport®
Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) Total Score at Week 4 [units: Scores on a Scale] Median (Full Range)		
Baseline	40.0 (19 to 70)	39.5 (25 to 68)
Week 4	22.0 (3 to 55)	25.0 (11 to 49)

3. Secondary Outcome Measure:

Measure Title	Physician Assessment of Cervical Dystonia Severity at Week 4
Measure Description	Physician assessment of cervical dystonia severity. The rating was assessed on a scale of 0 to 10, with higher scores denoting greater severity: 0 represented 'No evidence of dystonia' and 10 represented 'Worst cervical dystonia ever.'
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Modified intent to treat: all patients who were randomized to treatment and received 1 dose at Visit 1.

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Measured Values

	BOTOX®	Dysport®
Number of Participants Analyzed	75	70
Physician Assessment of Cervical Dystonia Severity at Week 4 [units: Units on a Scale] Median (Full Range)		
Baseline	6.0 (2 to 9)	7.0 (2 to 9)
Week 4	2.0 (1 to 7)	3.0 (1 to 7)

4. Secondary Outcome Measure:

Measure Title	Global Assessment of Benefit by Physician at Week 4
Measure Description	Physician evaluation of benefit from botulinum toxin type A treatment for cervical dystonia. Ratings were on a scale of +4 to -4, with higher scores denoting improvement in cervical dystonia: +4 was 'Complete abolishment of signs and symptoms (about 100% improvement)', 0 represented 'Unchanged', and -4 represented 'Very marked worsening (about 100% worse or greater).'
Time Frame	Week 4
Safety Issue?	No

Analysis Population Description

Modified intent to treat: all patients who were randomized to treatment and received 1 dose at Visit 1.

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Measured Values

	BOTOX®	Dysport®
Number of Participants Analyzed	75	70
Global Assessment of Benefit by Physician at Week 4 [units: Units on a Scale] Median (Full Range)	3.0 (-1 to 3)	3.0 (-1 to 3)

5. Secondary Outcome Measure:

Measure Title	Global Assessment of Benefit by Patient at Week 4
Measure Description	Patient evaluation of benefit from botulinum toxin type A treatment for cervical dystonia. Ratings were on a scale of +4 to -4, with higher scores denoting improvement in cervical dystonia: +4 was 'Complete abolishment of signs and symptoms (about 100% improvement)', 0 represented 'Unchanged', and -4 represented 'Very marked worsening (about 100% worse or greater).'
Time Frame	Week 4
Safety Issue?	No

Analysis Population Description

Modified intent to treat: all patients who were randomized to treatment and received 1 dose at Visit 1.

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Measured Values

	BOTOX®	Dysport®
Number of Participants Analyzed	75	70
Global Assessment of Benefit by Patient at Week 4 [units: Units on a Scale] Median (Full Range)	3.0 (-2 to 3)	3.0 (-1 to 3)

6. Secondary Outcome Measure:

Measure Title	Patient Assessment of Need for Retreatment at Week 4
Measure Description	Patients were queried regarding their need for another injection of botulinum toxin type A for cervical dystonia. Patients were required to answer "How would you rate your need for another injection of botulinum toxin type A for cervical dystonia using the following scale?". The response options included 'absolutely requires injection', 'very much requires injection', 'somewhat requires injection' and 'does not require injection'.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Modified intent to treat: all patients who were randomized to treatment and received 1 dose at Visit 1. Only completed assessments at the time points are included.

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Measured Values

	BOTOX®	Dysport®
Number of Participants Analyzed	73	69
Patient Assessment of Need for Retreatment at Week 4 [units: Number of Responses]		
Absolutely requires injection at Baseline	54	54
Very much requires injection at Baseline	19	15
Somewhat requires injection at Baseline	1	1
Does not require injection at Baseline	0	0
Absolutely requires injection at Week 4	17	15
Very much requires injection at Week 4	10	15
Somewhat requires injection at Week 4	18	18
Does not require injection at Week 4	2	21

7. Secondary Outcome Measure:

Measure Title	Patient Visual Analog Assessment of Pain at Week 4
Measure Description	Patients were required to assess their pain using a Visual Analog Scale in reference to their current perception of pain at that visit. This scale consisted of a line measuring 100 mm, and patients were instructed to put a mark on the line at the point that best described 'How much pain you are having right now'. Higher scores denoted higher pain intensity: 0 indicated 'No pain' and 100 indicated 'Worst possible pain'.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Modified intent to treat: all patients who were randomized to treatment and received 1 dose at Visit 1.

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Measured Values

	BOTOX®	Dysport®
Number of Participants Analyzed	75	70
Patient Visual Analog Assessment of Pain at Week 4 [units: Units on a Scale] Median (Full Range)		
Baseline	30.5 (0 to 100)	39.5 (0 to 92)
Week 4	8.0 (0 to 72)	13.0 (0 to 75)

8. Secondary Outcome Measure:

Measure Title	Physician Comparison of Benefit to Previous Injections at Week 10
Measure Description	Physicians assessed the improvement in cervical dystonia after the study treatment compared to previous treatment(s) for each patient. Physicians were required to answer "How would you rate the benefit of the current treatment of cervical dystonia with botulinum toxin type A compared to the previous treatment using the following scale?". The response options were 'much worse', 'worse', 'somewhat worse', 'same as previous', 'somewhat better', 'better', and 'much better'.
Time Frame	Week 10
Safety Issue?	No

Analysis Population Description

Modified intent to treat: all patients who were randomized to treatment and received 1 dose at Visit 1. Only completed assessments at this time point are included.

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Measured Values

	BOTOX®	Dysport®
Number of Participants Analyzed	73	69
Physician Comparison of Benefit to Previous Injections at Week 10 [units: Number of Responses]		

	BOTOX®	Dysport®
Much Worse	0	0
Worse	0	1
Somewhat Worse	7	7
Same as Previous	30	31
Somewhat Better	25	15
Better	7	12
Much Better	4	3

9. Secondary Outcome Measure:

Measure Title	Patient Comparison of Benefit to Previous Injections at Week 10
Measure Description	Patients assessed the improvement in cervical dystonia after receiving the study treatment compared to previous treatment(s). Patients were required to answer "How would you rate the benefit of the current treatment of cervical dystonia with botulinum toxin type A compared to the previous treatment using the following scale?". The response options were 'much worse', 'worse', 'somewhat worse', 'same as previous', 'somewhat better', 'better', and 'much better'.
Time Frame	Week 10
Safety Issue?	No

Analysis Population Description

Modified intent to treat: all patients who were randomized to treatment and received 1 dose at Visit 1. Only completed assessments at this timepoint are included.

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Measured Values

	BOTOX®	Dysport®
Number of Participants Analyzed	72	68
Patient Comparison of Benefit to Previous Injections at Week 10		

	BOTOX®	Dysport®
[units: Number of Responses]		
Much Worse	0	0
Worse	1	2
Somewhat Worse	8	10
Same as Previous	30	20
Somewhat Better	24	17
Better	8	12
Much Better	1	7

Reported Adverse Events

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

Reporting Groups

	Description
BOTOX®	botulinum toxin type A (BOTOX®)
Dysport®	botulinum toxin type A (Dysport®)

Serious Adverse Events

	BOTOX®	Dysport®
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/75 (0%)	0/70 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	BOTOX®	Dysport®
	Affected/At Risk (%)	Affected/At Risk (%)
Total	5/75 (6.67%)	4/70 (5.71%)
Gastrointestinal disorders		
Dysphagia [A] *	5/75 (6.67%)	4/70 (5.71%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (12.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

A disclosure restriction on the PI is that the sponsor can review results communications prior to public release for a period that is not less than 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication.

Results Point of Contact:

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