ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
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Study Identification

Unique Protocol ID:	AGN/HO/SPA/001-191622
Brief Title:	BOTOX® Economic Spasticity Trial (BEST)
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	July 2012
Overall Status:	Completed
Study Start:	October 2007
Primary Completion:	January 2010 [Actual]
Study Completion:	July 2010 [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: S5/2007 Board Name: Ethik-Kommission der Landesärztekammer Brandenburg Board Affiliation: Ethik-Kommission der Landesärztekammer Brandenburg Phone: +49 335 780 1053 Email: ethic@lankb.de
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Germany: Federal Institute for Drugs and Medical Devices Sweden: Medical Products Agency United Kingdom: Medicines and Healthcare Products Regulatory Agency Canada: Health Canada

Study Description

Brief Summary:	This is a study to investigate if patients who have had a stroke and suffer from spasticity might benefit from being given BOTOX® in addition to the normal Standard Care. Spasticity is characterized by stiffness or frequent cramps accompanied by pain and abnormal movements and can prevent the carrying out of everyday tasks such as walking and getting dressed. BOTOX® is a neurotoxin, which is used to prevent the contraction of muscle fibre and has been shown to reduce spasticity significantly. Patients will be enrolled in this study at about 33 locations in Europe and Canada. Study participation will last for about 1 year.
Detailed Description:	

Conditions

Conditions:	Muscle Spasticity
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)

Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	274 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Botulinum toxin type A 900kD First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.	Biological/Vaccine: Botulinum Toxin Type A 900kD The exact dosage and number of injection sites is based on the size, number, and location of muscles involved; the severity of spasticity; and the presence of local muscle weakness. First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit. Other Names: • BOTOX®
Placebo Comparator: Placebo First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.	Biological/Vaccine: Placebo The exact dosage and number of injection sites is based on the size, number, and location of muscles involved; the severity of spasticity; and the presence of local muscle weakness. First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	85 Years
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Patients with stroke due to a primary cerebral hemorrhage/infarction
- Subarachnoid hemorrhage producing an upper motor syndrome affecting one body side which results in a hemi-paralysis/ plegia

Exclusion Criteria:

- Patients with fixed contracture as a result of spasticity in the upper or lower limb planned to be treated and/or patients with other causes of spasticity (e.g. multiple sclerosis, spinal cord injury, etc.)

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan

Locations: United Kingdom
Burslem, Stoke-on-Trent, United Kingdom

Sweden
Uppsala, Sweden

Canada, Alberta
Edmonton, Alberta, Canada

Germany
Beelitz, Germany

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

	Description
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Overall Study

	Botulinum Toxin Type A 900kD	Placebo
Started	139	135
Completed	131	122
Not Completed	8	13

Baseline Characteristics

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Baseline Measures

	Botulinum Toxin Type A 900kD	Placebo	Total
Number of Participants	139	135	274
Age, Continuous [units: years] Median (Full Range)	64.11 (22.6 to 81.2)	61.86 (26.8 to 82.4)	62.60 (22.6 to 82.4)
Gender, Male/Female [units: participants]			
Female	54	59	113
Male	85	76	161

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Physician Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Active Functional Goal at Week 24
Measure Description	Physician assessment of success, as determined by percentage of patients who achieve their principal active functional goal (i.e. a score of 0 to +2 inclusive on the goal attainment scale [GAS]) at week 24 (or 10 weeks post second injection). The GAS is a 6-point scale where -3 means function is worse than at start, 0 means the expected goal was attained, and +2 is much better function than expected.
Time Frame	Week 24
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	139	134
Physician Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Active Functional Goal at Week 24 [units: Percentage of Patients]	40.9	33.3

2. Secondary Outcome Measure:

Measure Title	Physician Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 12

Measure Description	Physician assessment of success, as determined by percentage of patients who achieve their principal functional goal (i.e., a score of 0 to +2 inclusive on the goal attainment scale [GAS]) at week 12. The GAS is 6-point scale where -3 means function is worse than at start, 0 means the expected goal was attained, and +2 is much better function than expected.
Time Frame	Week 12
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	139	134
Physician Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 12 [units: Percentage of Patients]	33.1	28.9

3. Secondary Outcome Measure:

Measure Title	Physician Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 52
Measure Description	Physician assessment of success, as determined by percentage of patients who achieve their principal functional goal (i.e., a score of 0 to +2 inclusive on the goal attainment scale [GAS]) at week 52. The GAS is a 6-point scale where -3 means function is worse than at start, 0 means the expected goal was attained, and +2 is much better function than expected
Time Frame	Week 52
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	139	134
Physician Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 52 [units: Percentage of Patients]	45.0	52.4

4. Secondary Outcome Measure:

Measure Title	Patient Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 12
Measure Description	Patient assessment of success, as determined by percentage of patients who achieve their principal functional goal (i.e., a score of 0 to +2 inclusive on the goal attainment scale [GAS]) at week 12. The GAS is a 6-point scale where -3 means function is worse than at start, 0 means the expected goal was attained, and +2 is much better function than expected.
Time Frame	Week 12
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

	Description
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	139	134
Patient Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 12 [units: Percentage of Patients]	33.1	27.3

5. Secondary Outcome Measure:

Measure Title	Patient Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 24
Measure Description	Patient assessment of success, as determined by percentage of patients who achieve their principal functional goal (i.e., a score of 0 to +2 inclusive on the goal attainment scale [GAS]) at week 24 (or 10 weeks post second injection). The GAS is a 6-point scale where -3 means function is worse than at start, 0 means the expected goal was attained, and +2 is much better function than expected.
Time Frame	Week 24
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	139	134

	Botulinum Toxin Type A 900kD	Placebo
Patient Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 24 [units: Percentage of Patients]	40.7	39.0

6. Secondary Outcome Measure:

Measure Title	Patient Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 52
Measure Description	Patient assessment of success, as determined by percentage of patients who achieve their principal functional goal (i.e., a score of 0 to +2 inclusive on the goal attainment scale [GAS]) at week 52. The GAS is a 6-point scale where -3 means function is worse than at start, 0 means the expected goal was attained, and +2 is much better function than expected.
Time Frame	Week 52
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	139	134
Patient Assessment of Success, as Determined by Percentage of Patients Who Achieve Their Principal Functional Goal at Week 52 [units: Percentage of Patients]	48.9	50.8

7. Secondary Outcome Measure:

Measure Title	Activities of Daily Living Quality of Life (QOL) Score at Week 12
Measure Description	Activities of Daily Living QOL score at week 12 as measured by SF-12 Physical Component (PCS-12). The SF-12 consists of 12 questions on various health questions. The PCS-12 is a sub-score calculated from the SF-12 total score based on the physical health questions where 0 is worse and 100 is best. A higher score indicates a better health state.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	139	134
Activities of Daily Living Quality of Life (QOL) Score at Week 12 [units: Scores on a Scale] Mean (Standard Deviation)		
Baseline	48.81 (9.70)	46.40 (10.28)
Week 12	51.16 (9.10)	49.86 (9.82)

8. Secondary Outcome Measure:

Measure Title	Activities of Daily Living Quality of Life (QOL) Score at Week 24
Measure Description	Activities of daily living QOL score at week 24 (or 10 weeks post second injection) as measured by SF-12 Physical Component (PCS-12). The SF-12 consists of 12 questions on various health questions. The PCS-12 is a sub-score calculated from the SF-12 total score based on the physical health questions where 0 is worse and 100 is best. A higher score indicates a better health state.

Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	139	134
Activities of Daily Living Quality of Life (QOL) Score at Week 24 [units: Scores on a Scale] Mean (Standard Deviation)		
Baseline	48.81 (9.70)	46.40 (10.28)
Week 24	52.34 (10.03)	49.22 (10.36)

9. Secondary Outcome Measure:

Measure Title	Activities of Daily Living Quality of Life (QOL) Score at Week 52
Measure Description	Activities of daily living QOL score at week 52 as measured by SF-12 Physical Component (PCS-12). The SF-12 consists of 12 questions on various health questions. The PCS-12 is a sub-score calculated from the SF-12 total score based on the physical health questions where 0 is worse and 100 is best. A higher score indicates a better health state.
Time Frame	Baseline, Week 52
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	139	134
Activities of Daily Living Quality of Life (QOL) Score at Week 52 [units: Scores on a Scale] Mean (Standard Deviation)		
Baseline	48.81 (9.70)	46.40 (10.28)
Week 52	51.90 (9.44)	50.34 (10.03)

10. Secondary Outcome Measure:

Measure Title	Direct Costs for Canada
Measure Description	Direct healthcare costs associated with spasticity in cases where the primary reason for the use of the identified health care resource was the treatment of spasticity, or any related complications. Direct healthcare costs are presented in the local currency for Canada.
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients in Canada who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	12	10
Direct Costs for Canada [units: Canadian dollar (CAD)] Mean (Standard Deviation)	18643 (15022.4)	13279 (10827.9)

11. Secondary Outcome Measure:

Measure Title	Direct Costs for Germany
Measure Description	Direct healthcare costs associated with spasticity in cases where the primary reason for the use of the identified health care resource was the treatment of spasticity, or any related complications. Direct healthcare costs are presented in the local currency for Germany.
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients in Germany who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	34	34
Direct Costs for Germany [units: Euro (EUR)] Mean (Standard Deviation)	10181 (8110.1)	10346 (7468.6)

12. Secondary Outcome Measure:

Measure Title	Direct Costs for Sweden
Measure Description	Direct healthcare costs associated with spasticity in cases where the primary reason for the use of the identified health care resource was the treatment of spasticity, or any related complications. Direct healthcare costs are presented in the local currency for Sweden.
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients in Sweden who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	48	44
Direct Costs for Sweden [units: Swedish Krona (SEK)] Mean (Standard Deviation)	93916 (75122.3)	79580 (74951.3)

13. Secondary Outcome Measure:

Measure Title	Direct Costs for the United Kingdom
Measure Description	Direct healthcare costs associated with spasticity in cases where the primary reason for the use of the identified health care resource was the treatment of spasticity, or any related complications. Direct healthcare costs are presented in the local currency for the United Kingdom.
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

Intent-to-treat, which consists of all patients in the United Kingdom who were randomized (started study) and received a baseline injection.

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Measured Values

	Botulinum Toxin Type A 900kD	Placebo
Number of Participants Analyzed	45	46
Direct Costs for the United Kingdom [units: British Pound (GBP)] Mean (Standard Deviation)	4671 (6116.6)	3977 (4039.2)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	The Safety Population included all patients who were randomized and received at least 1 injection

Reporting Groups

	Description
Botulinum Toxin Type A 900kD	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.
Placebo	First intra-muscular injection at the Baseline visit, and optional second injection of the randomised treatment after a minimum of 12 weeks to a maximum of 24 weeks following the Baseline visit.

Serious Adverse Events

	Botulinum Toxin Type A 900kD	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	47/139 (33.81%)	45/134 (33.58%)
Blood and lymphatic system disorders		

	Botulinum Toxin Type A 900kD	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Anaemia Megaloblastic [A] †	1/139 (0.72%)	0/134 (0%)
Cardiac disorders		
Angina Pectoris [A] *	0/139 (0%)	2/134 (1.49%)
Atrial Fibrillation [A] †	1/139 (0.72%)	1/134 (0.75%)
Cardiac Failure [A] †	1/139 (0.72%)	2/134 (1.49%)
Left Ventricular Failure [A] †	1/139 (0.72%)	0/134 (0%)
Myocardial Infarction [A] †	0/139 (0%)	2/134 (1.49%)
Myocardial Ischaemia [A] †	0/139 (0%)	1/134 (0.75%)
Ear and labyrinth disorders		
Vertigo [A] *	0/139 (0%)	1/134 (0.75%)
Gastrointestinal disorders		
Colitis [A] †	0/139 (0%)	1/134 (0.75%)
Gastric Ulcer [A] †	1/139 (0.72%)	0/134 (0%)
General disorders		
Adverse Drug Reaction [A] †	0/139 (0%)	1/134 (0.75%)
Non-cardiac Chest Pain [A] *	1/139 (0.72%)	0/134 (0%)
Pyrexia [A] †	1/139 (0.72%)	0/134 (0%)
Hepatobiliary disorders		
Cholangitis [A] †	0/139 (0%)	1/134 (0.75%)
Infections and infestations		
Escherichia Infection [A] †	1/139 (0.72%)	0/134 (0%)
Labyrinthitis [A] †	0/139 (0%)	1/134 (0.75%)
Lower Respiratory Tract Infection [A] †	2/139 (1.44%)	0/134 (0%)

	Botulinum Toxin Type A 900kD	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Pneumonia [A] †	2/139 (1.44%)	4/134 (2.99%)
Sepsis [A] †	1/139 (0.72%)	0/134 (0%)
Upper Respiratory Tract Infection [A] †	0/139 (0%)	1/134 (0.75%)
Urinary Tract Infection [A] †	2/139 (1.44%)	1/134 (0.75%)
Injury, poisoning and procedural complications		
Ankle Fracture [A] †	1/139 (0.72%)	0/134 (0%)
Fall [A] *	3/139 (2.16%)	0/134 (0%)
Femoral Neck Fracture [A] †	1/139 (0.72%)	1/134 (0.75%)
Hip Fracture [A] †	2/139 (1.44%)	1/134 (0.75%)
Humerus Fracture [A] †	1/139 (0.72%)	1/134 (0.75%)
Pelvic Fracture [A] †	0/139 (0%)	1/134 (0.75%)
Radius Fracture [A] †	0/139 (0%)	1/134 (0.75%)
Rib Fracture [A] †	0/139 (0%)	1/134 (0.75%)
Subdural Haematoma [A] †	1/139 (0.72%)	0/134 (0%)
Tibia Fracture [A] †	0/139 (0%)	1/134 (0.75%)
Musculoskeletal and connective tissue disorders		
Polymyalgia Rheumatica [A] †	0/139 (0%)	1/134 (0.75%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast Cancer [A] †	1/139 (0.72%)	0/134 (0%)
Gammopathy [A] †	0/139 (0%)	1/134 (0.75%)
Uterine Leiomyoma [A] †	1/139 (0.72%)	0/134 (0%)
Nervous system disorders		
Cerebral Infarction [A] †	1/139 (0.72%)	2/134 (1.49%)

	Botulinum Toxin Type A 900kD	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Cerebrovascular Accident [A] †	1/139 (0.72%)	1/134 (0.75%)
Cognitive Disorder [A] †	1/139 (0.72%)	0/134 (0%)
Convulsion [A] †	3/139 (2.16%)	1/134 (0.75%)
Depressed Level of Consciousness [A] †	1/139 (0.72%)	0/134 (0%)
Dizziness [A] *	1/139 (0.72%)	2/134 (1.49%)
Epilepsy [A] †	2/139 (1.44%)	4/134 (2.99%)
Hemiparesis [A] †	1/139 (0.72%)	0/134 (0%)
Lacunar Infarction [A] †	1/139 (0.72%)	0/134 (0%)
Muscle Spasticity [A] †	1/139 (0.72%)	0/134 (0%)
Partial Seizures [A] †	0/139 (0%)	1/134 (0.75%)
Transient Ischaemic Attack [A] †	1/139 (0.72%)	0/134 (0%)
Renal and urinary disorders		
Renal Failure [A] †	1/139 (0.72%)	0/134 (0%)
Urinary Incontinence [A] *	0/139 (0%)	1/134 (0.75%)
Urinary Retention [A] *	0/139 (0%)	1/134 (0.75%)
Reproductive system and breast disorders		
Prostatitis [A] †	1/139 (0.72%)	0/134 (0%)
Respiratory, thoracic and mediastinal disorders		
Haemoptysis [A] *	0/139 (0%)	1/134 (0.75%)
Pulmonary Oedema [A] †	0/139 (0%)	1/134 (0.75%)
Respiratory Disorder [A] *	1/139 (0.72%)	0/134 (0%)
Skin and subcutaneous tissue disorders		
Swelling Face [A] *	1/139 (0.72%)	0/134 (0%)

	Botulinum Toxin Type A 900kD	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Vascular disorders		
Circulatory Collapse [A] †	0/139 (0%)	2/134 (1.49%)
Haematoma [A] †	1/139 (0.72%)	0/134 (0%)
Hypotension [A] †	1/139 (0.72%)	0/134 (0%)
Temporal Arteritis [A] †	1/139 (0.72%)	0/134 (0%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (13.0)

Other Adverse Events

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

	Botulinum Toxin Type A 900kD	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	60/139 (43.17%)	45/134 (33.58%)
Infections and infestations		
Nasopharyngitis [A] †	13/139 (9.35%)	11/134 (8.21%)
Upper Respiratory Tract Infection [A] †	3/139 (2.16%)	8/134 (5.97%)
Urinary Tract Infection [A] †	12/139 (8.63%)	7/134 (5.22%)
Injury, poisoning and procedural complications		
Fall [A] *	18/139 (12.95%)	15/134 (11.19%)
Musculoskeletal and connective tissue disorders		
Muscular Weakness [A] *	7/139 (5.04%)	1/134 (0.75%)
Pain in Extremity [A] *	7/139 (5.04%)	3/134 (2.24%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (13.0)

Limitations and Caveats

[Not specified]

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.

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