ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 11/16/2012

ClinicalTrials.gov ID: NCT00284518

Study Identification

Unique Protocol ID:	191622-517
Brief Title:	Safety and Efficacy Study of Botulinum Toxin Type A to Treat Lower Urinary Symptoms Due to Benign Prostatic Hyperplasia
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	November 2012
Overall Status:	Completed
Study Start:	December 2005
Primary Completion:	May 2009 [Actual]
Study Completion:	May 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: 12/12/2005 Board Name: Institutional Review Board Services Board Affiliation: Institutional Review Board Services Phone: 905-727-7989 Email: germainedance@irbservices.com
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	Canada: Health Canada

Study Description

Brief Summary:	The purpose of this study was to determine the safety and effectiveness of different doses of botulinum toxin Type A in treating lower urinary tract symptoms due to benign prostatic hyperplasia.
Detailed Description:	

Conditions

Conditions:	Benign Prostatic Hyperplasia
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	4
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	380 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: botulinum toxin Type A 300 U Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.	Biological/Vaccine: botulinum toxin Type A Botulinum toxin Type A 300 U, 200 U or 100 U transperineal or transrectal injection on Day 1. Other Names: • BOTOX®
Experimental: botulinum toxin Type A 200 U Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.	Biological/Vaccine: botulinum toxin Type A Botulinum toxin Type A 300 U, 200 U or 100 U transperineal or transrectal injection on Day 1. Other Names: • BOTOX®
Experimental: botulinum toxin Type A 100 U Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.	Biological/Vaccine: botulinum toxin Type A Botulinum toxin Type A 300 U, 200 U or 100 U transperineal or transrectal injection on Day 1. Other Names: • BOTOX®
Placebo Comparator: Placebo (Normal Saline) Placebo (Normal Saline) transperineal or transrectal injection on Day 1.	Drug: normal saline Normal Saline (Placebo) transperineal or transrectal injection on Day 1.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Gender: Male

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Lower urinary tract symptoms due to benign prostatic hyperplasia
- Enlarged prostate volume by rectal ultrasound

Exclusion Criteria:

- Previous prostate surgery

- Previous or current diagnosis of prostate cancer
- Use of other medications for the treatment of prostatic hyperplasia
- Urinary tract infection

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan

Locations: Canada, British Columbia
Victoria, British Columbia, Canada

Austria
Vienna, Austria

Czech Republic
Olomouc, Czech Republic

France
Paris Cedex 13, France

Taiwan
Taipei, Taiwan

Germany
Braunschweig, Germany

Italy
Perugia, Italy

Slovakia
Martin, Slovakia

United Kingdom
London, United Kingdom

Australia
Murdoch, Australia

Korea, Republic of
Seoul, Korea, Republic of

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Overall Study

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Started	97	94	95	94
Completed	71	66	67	61
Not Completed	26	28	28	33

Baseline Characteristics

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.

	Description
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Baseline Measures

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)	Total
Number of Participants	97	94	95	94	380
Age, Customized [units: Participants]					
45 to 65 Years	48	46	56	44	194
>65 Years	49	48	39	50	186
Gender, Male/Female [units: Participants]					
Female	0	0	0	0	0
Male	97	94	95	94	380

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in International Prostate Symptom Score (IPSS) at Week 12
Measure Description	The International Prostate Symptom Score is a disease-specific outcome measure based on the American Urological Association Symptom Index. The questionnaire consists of seven items. The patient evaluates their urinary symptoms (incomplete emptying, frequency, hesitancy, urgency, weak stream, straining, and nocturia) during the previous 4 weeks. The total symptom score can range from 0 (no symptoms) to 35 (most severe symptoms). A negative change from baseline indicates improvement.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Participants from the intent-to-treat population (includes all randomized participants) with data available for analyses at the given time-point.

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.

	Description
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Measured Values

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Number of Participants Analyzed	89	91	94	92
Change From Baseline in International Prostate Symptom Score (IPSS) at Week 12 [units: Score on a scale] Mean (Standard Deviation)				
Baseline	21.3 (6.03)	20.2 (5.80)	21.5 (5.42)	20.7 (5.44)
Change from baseline at Week 12 (N=86,89,93,90)	-5.6 (7.73)	-6.3 (7.13)	-6.6 (6.87)	-5.5 (6.33)

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in International Prostate Symptom Score (IPSS) at Week 72
Measure Description	The International Prostate Symptom Score is a disease-specific outcome measure based on the American Urological Association Symptom Index. The questionnaire consists of seven items. The patient evaluates their urinary symptoms (incomplete emptying, frequency, hesitancy, urgency, weak stream, straining, and nocturia) during the previous 4 weeks. The total symptom score can range from 0 (no symptoms) to 35 (most severe symptoms). A negative change from baseline indicates improvement.
Time Frame	Baseline, Week 72
Safety Issue?	No

Analysis Population Description

Participants from the intent-to-treat population (includes all randomized participants) with data available for analyses at the given time-point.

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.

	Description
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Measured Values

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Number of Participants Analyzed	89	91	94	92
Change From Baseline in International Prostate Symptom Score (IPSS) at Week 72 [units: Score on a scale] Mean (Standard Deviation)				
Baseline	21.3 (6.03)	20.2 (5.80)	21.5 (5.42)	20.7 (5.44)
Change from baseline at Week 72 (N=64,61,66,58)	-5.0 (6.50)	-4.1 (6.40)	-4.7 (7.15)	-4.3 (7.15)

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Peak Urine Flow Rate
Measure Description	Urinary flow was determined by uroflowmetry at baseline and various time-points during the study. An increase from baseline indicates improvement.
Time Frame	Baseline, Week 12, Week 72
Safety Issue?	No

Analysis Population Description

Participants from the intent-to-treat population (includes all randomized participants) with data available for analyses at the given time-point.

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Measured Values

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Number of Participants Analyzed	95	89	93	91
Change From Baseline in Peak Urine Flow Rate [units: milliliters (mL)/second] Mean (Standard Deviation)				
Baseline	10.4 (2.70)	10.6 (2.83)	9.6 (2.57)	10.1 (2.82)
Change from baseline to Week 12 (N=81,80,86,77)	1.8 (4.65)	2.0 (4.98)	2.7 (5.21)	2.8 (4.74)
Change from baseline to Week 72 (N=59,56,64,53)	2.0 (4.67)	2.4 (5.18)	2.0 (4.07)	2.3 (4.31)

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Total Prostate Volume
Measure Description	Measurement of the prostate volume was performed via transrectal ultrasound at baseline and various time-points during the study. The prostate gland was scanned and the volume was calculated using the formula: Volume (mL) = length × width × height × 0.523. A negative change from baseline indicates improvement.
Time Frame	Baseline, Week 12, Week 72
Safety Issue?	No

Analysis Population Description

Participants from the intent-to-treat population (includes all randomized participants) with data available for analyses at the given time-point.

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Measured Values

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Number of Participants Analyzed	96	91	92	91

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Change From Baseline in Total Prostate Volume [units: milliliter (mL)] Mean (Standard Deviation)				
Baseline	48.78 (16.800)	48.40 (16.325)	47.54 (16.917)	47.23 (14.867)
Change from baseline at Week 12 (N=86,84,88,82)	-3.40 (10.046)	-3.65 (9.255)	-3.54 (9.823)	-4.59 (8.392)
Change from baseline at Week 72 (N=65,60,67,57)	-3.58 (9.773)	-2.82 (11.194)	-1.77 (10.714)	-2.69 (10.875)

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in Transitional Zone Prostate Volume
Measure Description	Measurement of the transitional zone prostate volume was performed via transrectal ultrasound at baseline and various time-points during the study. The prostate gland was scanned and the volume was calculated using the formula: Volume (mL) = length × width × height × 0.523. A negative change from baseline indicates improvement.
Time Frame	Baseline, Week 12, Week 72
Safety Issue?	No

Analysis Population Description

Participants from the intent-to-treat population (includes all randomized participants) with data available for analyses at the given time-point.

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Measured Values

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Number of Participants Analyzed	94	89	90	87
Change From Baseline in Transitional Zone Prostate Volume				

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
[units: milliliters (mL)] Mean (Standard Deviation)				
Baseline	20.78 (14.657)	21.75 (12.931)	21.00 (14.188)	20.73 (13.210)
Change from baseline at Week 12 (N=83,82,86,79)	-0.23 (6.516)	-0.76 (8.085)	-0.02 (8.445)	-0.27 (6.551)
Change from baseline at Week 72 (N=64,59,65,55)	0.19 (7.655)	-0.94 (8.119)	-0.35 (8.808)	-1.35 (6.801)

6. Secondary Outcome Measure:

Measure Title	Change From Baseline in Post-Void Residual
Measure Description	Post-void residual urine volume was assessed by bladder scan or ultrasound on all participants at baseline and various time-points during the study. After voiding, any residual urine volume in the bladder was measured. A negative change from baseline indicates improvement.
Time Frame	Baseline, Week 2, Week 12, Week 72
Safety Issue?	No

Analysis Population Description

Participants from the safety population (includes all randomized and treated participants) with data available for analyses at the given time-point.

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Measured Values

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Number of Participants Analyzed	92	89	89	91
Change From Baseline in Post-Void Residual [units: milliliters (mL)] Mean (Standard Deviation)				

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Baseline	73.0 (57.07)	69.7 (54.93)	66.1 (55.59)	64.3 (51.89)
Change from baseline at Week 2 (N=76,82,80,78)	5.4 (64.06)	10.9 (88.62)	-1.4 (65.01)	1.6 (61.03)
Change from baseline at Week 12 (N=88,84,89,82)	7.5 (78.18)	9.0 (81.23)	-1.4 (62.82)	3.2 (57.92)
Change from baseline at Week 72 (N=66,60,65,60)	10.9 (73.27)	-12.4 (54.31)	14.0 (75.97)	6.0 (69.79)

7. Other Pre-specified Outcome Measure:

Measure Title	Change From Baseline in the International Index of Erectile Function (IIEF) Questionnaire Erectile Function Domain
Measure Description	The IIEF is a 15-item questionnaire filled out by the patient to assess erectile function over the past 4 weeks that contains five domains. The score for the erectile function domain is the sum of scores for Questions 1, 2, 3, 4, 5 and 15 for a total possible score of 1 to 30. A higher score indicates a better outcome. A positive change from baseline indicates improvement.
Time Frame	Baseline, Week 12, Week 72
Safety Issue?	No

Analysis Population Description

Participants from the intent-to-treat population (includes all randomized participants) with data available for analyses at the given time-point.

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Measured Values

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Number of Participants Analyzed	86	79	84	87
Change From Baseline in the International Index of Erectile Function (IIEF) Questionnaire Erectile Function Domain				

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
[units: Score on a scale] Mean (Standard Deviation)				
Baseline	15.4 (10.20)	14.6 (10.7)	17.2 (10.19)	16.7 (10.29)
Change from baseline at Week 12 (N=80,72,83,79)	0.1 (6.66)	-0.2 (5.54)	-0.9 (6.93)	1.3 (7.86)
Change from baseline at Week 72 (N=61,54,61,58)	0.8 (7.17)	0.5 (4.56)	-1.5 (7.34)	-0.9 (7.95)

8. Post-Hoc Outcome Measure:

Measure Title	Change From Baseline in IPSS at Week 12 in Patients Previously Treated With Alpha-blockers
Measure Description	The International Prostate Symptom Score (IPSS) is a disease-specific outcome measure based on the American Urological Association Symptom Index. The questionnaire consists of seven items. The patient evaluates their urinary symptoms (incomplete emptying, frequency, hesitancy, urgency, weak stream, straining, and nocturia) during the previous 4 weeks. The total symptom score can range from 0 (no symptoms) to 35 (most severe symptoms). A negative change from baseline indicates improvement.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Participants from the Intent-to-treat population previously treated with alpha-blockers with data available for analyses.

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Measured Values

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Number of Participants Analyzed	44	35	52	43

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
Change From Baseline in IPSS at Week 12 in Patients Previously Treated With Alpha-blockers [units: Score on a scale] Mean (Standard Deviation)				
Baseline	21.3 (6.20)	19.6 (6.15)	21.9 (5.65)	20.4 (5.32)
Change from baseline at Week 12 (N=44,35,52,42)	-5.1 (7.76)	-6.6 (5.91)	-5.4 (5.17)	-3.5 (6.12)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Safety population was used to calculate the number of participants at risk for Serious Adverse Events and Adverse Events and was defined as all randomized and treated participants.

Reporting Groups

	Description
Botulinum Toxin Type A 300 U	Botulinum toxin Type A 300 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 200 U	Botulinum toxin Type A 200 U transperineal or transrectal injection on Day 1.
Botulinum Toxin Type A 100 U	Botulinum toxin Type A 100 U transperineal or transrectal injection on Day 1.
Placebo (Normal Saline)	Placebo (Normal Saline) transperineal or transrectal injection on Day 1.

Serious Adverse Events

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	9/94 (9.57%)	16/93 (17.2%)	10/94 (10.64%)	11/92 (11.96%)
Cardiac disorders				
Acute coronary syndrome [A] †	0/94 (0%)	0/93 (0%)	2/94 (2.13%)	0/92 (0%)
Angina pectoris [A] †	0/94 (0%)	2/93 (2.15%)	0/94 (0%)	0/92 (0%)

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Angina unstable [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (0%)
Myocardial infarction [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (0%)
Eye disorders				
Blindness unilateral [A] *	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Corneal degeneration [A] †	0/94 (0%)	0/93 (0%)	0/94 (0%)	1/92 (1.09%)
Retinal artery thrombosis [A] †	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Gastrointestinal disorders				
Gastritis [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (0%)
Inguinal hernia [A] †	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Intestinal obstruction [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (0%)
General disorders				
Accidental death [A] †	0/94 (0%)	2/93 (2.15%)	0/94 (0%)	0/92 (0%)
Non-cardiac chest pain [A] *	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Hepatobiliary disorders				
Cholecystitis acute [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (0%)
Cholelithiasis [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (0%)
Infections and infestations				
Bacterial prostatitis [A] †	0/94 (0%)	0/93 (0%)	0/94 (0%)	1/92 (1.09%)
Cellulitis [A] †	0/94 (0%)	0/93 (0%)	0/94 (0%)	1/92 (1.09%)
Herpes zoster [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (0%)
Injury, poisoning and procedural complications				
Femur fracture [A] †	1/94 (1.06%)	0/93 (0%)	0/94 (0%)	0/92 (0%)

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Investigations				
Prostatic specific antigen increased [A] †	1/94 (1.06%)	0/93 (0%)	0/94 (0%)	0/92 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] *	0/94 (0%)	0/93 (0%)	0/94 (0%)	1/92 (1.09%)
Arthritis [A] †	1/94 (1.06%)	0/93 (0%)	0/94 (0%)	0/92 (0%)
Intervertebral disc protrusion [A] †	1/94 (1.06%)	0/93 (0%)	0/94 (0%)	0/92 (0%)
Osteoarthritis [A] †	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	2/92 (2.17%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Basal cell carcinoma [A] †	0/94 (0%)	0/93 (0%)	0/94 (0%)	1/92 (1.09%)
Gastric adenoma [A] †	0/94 (0%)	0/93 (0%)	0/94 (0%)	1/92 (1.09%)
Gastric cancer [A] †	0/94 (0%)	0/93 (0%)	0/94 (0%)	1/92 (1.09%)
Metastatic neoplasm [A] †	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Prostate cancer [A] †	1/94 (1.06%)	0/93 (0%)	0/94 (0%)	0/92 (0%)
Renal cancer [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (0%)
Renal cell carcinoma [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	1/92 (1.09%)
Nervous system disorders				
Carotid artery stenosis [A] †	0/94 (0%)	0/93 (0%)	0/94 (0%)	1/92 (1.09%)
Hypoaesthesia [A] *	1/94 (1.06%)	0/93 (0%)	0/94 (0%)	0/92 (0%)
Psychiatric disorders				
Alcoholism [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (0%)
Anxiety [A] *	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Renal and urinary disorders				

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Calculus bladder [A] †	2/94 (2.13%)	0/93 (0%)	0/94 (0%)	0/92 (0%)
Calculus ureteric [A] †	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Hydronephrosis [A] †	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Nephrolithiasis [A] †	1/94 (1.06%)	0/93 (0%)	0/94 (0%)	0/92 (0%)
Urinary retention [A] *	1/94 (1.06%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	1/92 (1.09%)
Prostatitis [A] †	1/94 (1.06%)	2/93 (2.15%)	1/94 (1.06%)	0/92 (0%)
Respiratory, thoracic and mediastinal disorders				
Pleural effusion [A] †	0/94 (0%)	0/93 (0%)	1/94 (1.06%)	0/92 (0%)
Vascular disorders				
Hypertensive crisis [A] †	0/94 (0%)	1/93 (1.08%)	0/94 (0%)	0/92 (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 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	41/94 (43.62%)	46/93 (49.46%)	53/94 (56.38%)	55/92 (59.78%)
Infections and infestations				
Nasopharyngitis [A] †	5/94 (5.32%)	6/93 (6.45%)	5/94 (5.32%)	5/92 (5.43%)
Urinary tract infection [A] †	6/94 (6.38%)	1/93 (1.08%)	4/94 (4.26%)	3/92 (3.26%)
Investigations				

	Botulinum Toxin Type A 300 U	Botulinum Toxin Type A 200 U	Botulinum Toxin Type A 100 U	Placebo (Normal Saline)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Prostatic specific antigen increase [A] †	5/94 (5.32%)	5/93 (5.38%)	3/94 (3.19%)	5/92 (5.43%)
Musculoskeletal and connective tissue disorders				
Back pain [A] *	1/94 (1.06%)	5/93 (5.38%)	2/94 (2.13%)	3/92 (3.26%)
Renal and urinary disorders				
Dysuria [A] *	2/94 (2.13%)	5/93 (5.38%)	4/94 (4.26%)	3/92 (3.26%)
Haematuria [A] †	4/94 (4.26%)	7/93 (7.53%)	8/94 (8.51%)	8/92 (8.7%)
Micturition urgency [A] *	1/94 (1.06%)	3/93 (3.23%)	5/94 (5.32%)	6/92 (6.52%)
Pollakiuria [A] *	1/94 (1.06%)	2/93 (2.15%)	2/94 (2.13%)	5/92 (5.43%)
Renal cyst [A] †	7/94 (7.45%)	2/93 (2.15%)	7/94 (7.45%)	3/92 (3.26%)
Urinary retention [A] †	2/94 (2.13%)	2/93 (2.15%)	5/94 (5.32%)	3/92 (3.26%)
Reproductive system and breast disorders				
Haematospermia [A] †	2/94 (2.13%)	6/93 (6.45%)	5/94 (5.32%)	7/92 (7.61%)
Vascular disorders				
Hypertension [A] †	5/94 (5.32%)	2/93 (2.15%)	3/94 (3.19%)	4/92 (4.35%)

† 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.

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 and can embargo communications regarding trial results for a period that is less than or equal to 90 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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