ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 10/11/2013

ClinicalTrials.gov ID: NCT00168454

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | 191622-077 |
| Brief Title: | A Research Study for Patients With Overactive Bladder |
| Official Title: | |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | October 2013 |
| Overall Status: | Completed |
| Study Start: | July 2005 |
| Primary Completion: | January 2008 [Actual] |
| Study Completion: | June 2008 [Actual] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | Allergan |
| Responsible Party: | Sponsor |
| Collaborators: | |

## Oversight

| | |
|---|---|
| FDA Regulated?: | Yes |
| Applicable Trial?: | Section 801 Clinical Trial? Yes<br>Delayed Posting? No |

| | |
|---|---|
| IND/IDE Protocol?: | Yes |
| IND/IDE Information: | Grantor: CDER<br>IND/IDE Number: 12430<br>Serial Number:<br>Has Expanded Access? No |
| Review Board: | Approval Status:<br>Board Name:<br>Board Affiliation:<br>Phone:<br>Email: |
| Data Monitoring?: | Yes |
| Plan to Share Data?: | |
| Oversight Authorities: | United States: Food and Drug Administration |

## Study Description

| | |
|---|---|
| Brief Summary: | The purpose of this study is to investigate whether injections of botulinum toxin Type A into the bladder are safe and effective in treating overactive bladder. |
| Detailed Description: | |

## Conditions

| | |
|---|---|
| Conditions: | Overactive Bladder<br>Urinary Incontinence |
| Keywords: | |

## Study Design

| | |
|---|---|
| Study Type: | Interventional |
| Primary Purpose: | Treatment |
| Study Phase: | Phase 2 |
| Intervention Model: | Parallel Assignment |
| Number of Arms: | 6 |
| Masking: | Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor) |
| Allocation: | Randomized |

Endpoint Classification: Safety/Efficacy Study

Enrollment: 313 [Actual]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Placebo Comparator: Placebo<br>Placebo (normal saline) injected into detrusor on Day 1 | Drug: Placebo<br>Placebo (normal saline) injected into detrusor on Day 1 |
| Experimental: BOTOX 50 U<br>botulinum toxin Type A 50 U injected into detrusor on Day 1 | Biological/Vaccine: botulinum toxin Type A<br>botulinum toxin Type A injected into detrusor on Day 1<br>Other Names:<br>• BOTOX® |
| Experimental: BOTOX 100 U<br>botulinum toxin Type A 100 U injected into detrusor on Day 1 | Biological/Vaccine: botulinum toxin Type A<br>botulinum toxin Type A injected into detrusor on Day 1<br>Other Names:<br>• BOTOX® |
| Experimental: BOTOX 150 U<br>botulinum toxin Type A 150 U injected into detrusor on Day 1 | Biological/Vaccine: botulinum toxin Type A<br>botulinum toxin Type A injected into detrusor on Day 1<br>Other Names:<br>• BOTOX® |
| Experimental: BOTOX 200 U<br>botulinum toxin Type A 200 U injected into detrusor on Day 1 | Biological/Vaccine: botulinum toxin Type A<br>botulinum toxin Type A injected into detrusor on Day 1<br>Other Names:<br>• BOTOX® |
| Experimental: BOTOX 300 U<br>botulinum toxin Type A 300 U injected into detrusor on Day 1 | Biological/Vaccine: botulinum toxin Type A<br>botulinum toxin Type A injected into detrusor on Day 1<br>Other Names:<br>• BOTOX® |

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 18 Years

| | |
|---|---|
| Maximum Age: | 85 Years |
| Gender: | Both |
| Accepts Healthy Volunteers?: | No |
| Criteria: | Inclusion Criteria: |

- Must be between 18-85 years old
- Must have been diagnosed by his/her doctor with overactive bladder at least 6 months ago
- Must weigh at least 50 kg (110 lbs)
- Must be willing and able to record information regarding bladder function into a diary (provided)
- Must be willing and able to complete the entire course of the study

Exclusion Criteria:

- Cannot currently be catheterizing as a way to control incontinence
- Must not have used botulinum toxin type A or any other botulinum toxin previously for any condition

## Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc.

Locations: United States, Pennsylvania
Pittsburgh, Pennsylvania, United States

Canada, British Columbia
Victoria, British Columbia, Canada

United Kingdom
Sheffield, United Kingdom

Germany
Berlin, Germany

Poland
Warsaw, Poland

Belgium
Ghent, Belgium

## References

Citations:

Links:

Study Data/Documents:

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# Study Results

## Participant Flow

Reporting Groups

| | Description |
|---|---|
| Placebo | Placebo (normal saline)injection on Day 1 into detrusor |
| BOTOX 50 U | botulinum toxin Type A 50 U injection on Day 1 into detrusor |
| BOTOX 100 U | botulinum toxin Type A 100 U injection on Day 1 into detrusor |
| BOTOX 150 U | botulinum toxin Type A 150 U injection on Day 1 into detrusor |
| BOTOX 200 U | botulinum toxin Type A 200 U injection on Day 1 into detrusor |
| BOTOX 300 U | botulinum toxin Type A 300 U injection on Day 1 into detrusor |

Overall Study

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| Started | 44 | 57 | 54 | 49 | 53 | 56 |
| Completed | 37 | 50 | 48 | 40 | 47 | 50 |
| Not Completed | 7 | 7 | 6 | 9 | 6 | 6 |

## Baseline Characteristics

Reporting Groups

| | Description |
|---|---|
| Placebo | Placebo (normal saline)injection on Day 1 into detrusor |

| | Description |
|---|---|
| BOTOX 50 U | botulinum toxin Type A 50 U injection on Day 1 into detrusor |
| BOTOX 100 U | botulinum toxin Type A 100 U injection on Day 1 into detrusor |
| BOTOX 150 U | botulinum toxin Type A 150 U injection on Day 1 into detrusor |
| BOTOX 200 U | botulinum toxin Type A 200 U injection on Day 1 into detrusor |
| BOTOX 300 U | botulinum toxin Type A 300 U injection on Day 1 into detrusor |

Baseline Measures

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U | Total |
|---|---|---|---|---|---|---|---|
| Number of Participants | 44 | 57 | 54 | 49 | 53 | 56 | 313 |
| Age, Customized [units: participants] | | | | | | | |
| <45 years | 7 | 9 | 6 | 8 | 6 | 6 | 42 |
| 45-64 years | 24 | 27 | 25 | 27 | 21 | 29 | 153 |
| 65-74 years | 6 | 13 | 16 | 12 | 20 | 15 | 82 |
| >=75 years | 7 | 8 | 7 | 2 | 6 | 6 | 36 |
| Gender, Male/Female [units: participants] | | | | | | | |
| Female | 40 | 53 | 50 | 47 | 46 | 52 | 288 |
| Male | 4 | 4 | 4 | 2 | 7 | 4 | 25 |

## Outcome Measures

1. Primary Outcome Measure:

| | |
|---|---|
| Measure Title | Change in Number of Urinary Urge Incontinence Episodes |
| Measure Description | Mean number of urinary urge incontinence episodes measured over a 7-day diary prior to week 12. Urinary urge incontinence is defined as urinary leakage associated with a strong desire to urinate. |
| Time Frame | Baseline, Week 2, Week 6, Week 12 |
| Safety Issue? | No |

Analysis Population Description

Intent to Treat

Reporting Groups

| | Description |
|---|---|
| Placebo | Placebo (normal saline)injection on Day 1 into detrusor |
| BOTOX 50 U | botulinum toxin Type A 50 U injection on Day 1 into detrusor |
| BOTOX 100 U | botulinum toxin Type A 100 U injection on Day 1 into detrusor |
| BOTOX 150 U | botulinum toxin Type A 150 U injection on Day 1 into detrusor |
| BOTOX 200 U | botulinum toxin Type A 200 U injection on Day 1 into detrusor |
| BOTOX 300 U | botulinum toxin Type A 300 U injection on Day 1 into detrusor |

Measured Values

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| Number of Participants Analyzed | 44 | 57 | 54 | 49 | 53 | 56 |
| Change in Number of Urinary Urge Incontinence Episodes<br>[units: episodes] | | | | | | |
| Baseline | 32.5 | 30.3 | 27.8 | 28.3 | 24.1 | 26.8 |
| Week 2 | -17.3 | -20.0 | -18.6 | -20.8 | -16.8 | -18.6 |
| Week 6 | -18.2 | -21.2 | -19.9 | -23.4 | -20.0 | -18.8 |
| Week 12 | -17.4 | -20.7 | -18.4 | -23.0 | -19.6 | -19.4 |

2. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change in Number of Micturitions |
| Measure Description | Mean number of micturitions measured over a 7 day diary prior to each visit. Micturation is defined as urinating into the toilet. |
| Time Frame | Baseline, Week 2, Week 6, Week 12 |
| Safety Issue? | No |

Analysis Population Description

Intent to Treat

Reporting Groups

| | Description |
|---|---|
| Placebo | Placebo (normal saline)injection on Day 1 into detrusor |
| BOTOX 50 U | botulinum toxin Type A 50 U injection on Day 1 into detrusor |
| BOTOX 100 U | botulinum toxin Type A 100 U injection on Day 1 into detrusor |
| BOTOX 150 U | botulinum toxin Type A 150 U injection on Day 1 into detrusor |
| BOTOX 200 U | botulinum toxin Type A 200 U injection on Day 1 into detrusor |
| BOTOX 300 U | botulinum toxin Type A 300 U injection on Day 1 into detrusor |

Measured Values

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| Number of Participants Analyzed | 44 | 57 | 54 | 49 | 53 | 56 |
| Change in Number of Micturitions<br>[units: micturitions] | | | | | | |
| Baseline | 73.3 | 76.3 | 80.3 | 76.5 | 76.7 | 75.6 |
| Week 2 | -6.5 | -10.0 | -12.5 | -9.8 | -7.2 | -9.2 |
| Week 6 | -9.4 | -15.2 | -22.9 | -17.0 | -18.9 | -19.9 |
| Week 12 | -8.3 | -15.3 | -21.7 | -18.8 | -19.7 | -21.2 |

3. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change in Number of Nocturia Episodes |
| Measure Description | Mean number of nocturia episodes measured over a 7 day diary prior to each visit. A nocturia episode is a void (urinating into the toilet) that interrupts one's sleep. |
| Time Frame | Baseline, Week 12 |
| Safety Issue? | No |

Analysis Population Description

Intent to Treat

Reporting Groups

| | Description |
|---|---|
| Placebo | Placebo (normal saline)injection on Day 1 into detrusor |
| BOTOX 50 U | botulinum toxin Type A 50 U injection on Day 1 into detrusor |
| BOTOX 100 U | botulinum toxin Type A 100 U injection on Day 1 into detrusor |
| BOTOX 150 U | botulinum toxin Type A 150 U injection on Day 1 into detrusor |
| BOTOX 200 U | botulinum toxin Type A 200 U injection on Day 1 into detrusor |
| BOTOX 300 U | botulinum toxin Type A 300 U injection on Day 1 into detrusor |

Measured Values

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| Number of Participants Analyzed | 44 | 57 | 54 | 49 | 53 | 56 |
| Change in Number of Nocturia Episodes [units: episodes] | | | | | | |
| Baseline | 12.3 | 12.2 | 13.9 | 17.9 | 12.2 | 14.9 |
| Week 12 | -0.3 | -2.5 | -4.1 | -6.5 | -3.8 | -7.0 |

4. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Maximum Cystometric Capacity (MCC) by Urodynamic Measurements |
| Measure Description | Maximum Cystometric Capacity (maximum volume that the bladder can hold) measured in mean milliliters |
| Time Frame | Baseline, Week 12 |
| Safety Issue? | No |

Analysis Population Description
Intent to Treat

Reporting Groups

| | Description |
|---|---|
| Placebo | Placebo (normal saline)injection on Day 1 into detrusor |
| BOTOX 50 U | botulinum toxin Type A 50 U injection on Day 1 into detrusor |

| | Description |
|---|---|
| BOTOX 100 U | botulinum toxin Type A 100 U injection on Day 1 into detrusor |
| BOTOX 150 U | botulinum toxin Type A 150 U injection on Day 1 into detrusor |
| BOTOX 200 U | botulinum toxin Type A 200 U injection on Day 1 into detrusor |
| BOTOX 300 U | botulinum toxin Type A 300 U injection on Day 1 into detrusor |

Measured Values

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| Number of Participants Analyzed | 44 | 57 | 54 | 49 | 53 | 56 |
| Maximum Cystometric Capacity (MCC) by Urodynamic Measurements [units: milliliters] | | | | | | |
| Baseline | 267.1 | 262.9 | 255.0 | 258.4 | 280.1 | 271.7 |
| Week 12 | 49.5 | 50.0 | 71.0 | 101.7 | 91.5 | 130.8 |

5. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Incontinence Quality of Life Instrument (I-QOL) |
| Measure Description | Measured on 3 domains; a 5-point scale (1-5) for each domain. Sum of the domain scores is normalized to a scale of 0-100 (100 = no impact of incontinence on daily activities, 0 = maximum impact of incontinence on daily activities). Mean scores presented. |
| Time Frame | Baseline, Week 2, Week 6, Week 12 |
| Safety Issue? | No |

Analysis Population Description

Intent to Treat

Reporting Groups

| | Description |
|---|---|
| Placebo | Placebo (normal saline)injection on Day 1 into detrusor |
| BOTOX 50 U | botulinum toxin Type A 50 U injection on Day 1 into detrusor |
| BOTOX 100 U | botulinum toxin Type A 100 U injection on Day 1 into detrusor |

| | Description |
|---|---|
| BOTOX 150 U | botulinum toxin Type A 150 U injection on Day 1 into detrusor |
| BOTOX 200 U | botulinum toxin Type A 200 U injection on Day 1 into detrusor |
| BOTOX 300 U | botulinum toxin Type A 300 U injection on Day 1 into detrusor |

Measured Values

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| Number of Participants Analyzed | 44 | 57 | 54 | 49 | 53 | 56 |
| Incontinence Quality of Life Instrument (I-QOL) [units: Units on a scale] | | | | | | |
| Baseline | 35.9 | 32.3 | 34.3 | 30.5 | 32.0 | 34.5 |
| Week 2 | 14.8 | 21.1 | 28.1 | 29.5 | 26.7 | 31.6 |
| Week 6 | 16.3 | 30.6 | 32.1 | 37.2 | 34.5 | 41.6 |
| Week 12 | 17.9 | 29.8 | 32.9 | 35.2 | 37.1 | 39.7 |

6. Post-Hoc Outcome Measure:

| | |
|---|---|
| Measure Title | Percentage of Patients With 100% Reduction From Baseline of Urinary Urge Incontinence Episodes |
| Measure Description | Measured by the 7 day diary preceding each visit. Urinary urge incontinence is defined as urinary leakage associated with a strong desire to urinate. |
| Time Frame | Baseline, Week 2, Week 6, Week 12, Week 18, Week 24, Week 30, Week 36 |
| Safety Issue? | No |

Analysis Population Description
Intent to Treat

Reporting Groups

| | Description |
|---|---|
| Placebo | Placebo (normal saline)injection on Day 1 into detrusor |
| BOTOX 50 U | botulinum toxin Type A 50 U injection on Day 1 into detrusor |
| BOTOX 100 U | botulinum toxin Type A 100 U injection on Day 1 into detrusor |

| | Description |
|---|---|
| BOTOX 150 U | botulinum toxin Type A 150 U injection on Day 1 into detrusor |
| BOTOX 200 U | botulinum toxin Type A 200 U injection on Day 1 into detrusor |
| BOTOX 300 U | botulinum toxin Type A 300 U injection on Day 1 into detrusor |

Measured Values

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| Number of Participants Analyzed | 44 | 57 | 54 | 49 | 53 | 56 |
| Percentage of Patients With 100% Reduction From Baseline of Urinary Urge Incontinence Episodes [units: Percentage of patients] | | | | | | |
| Week 2 | 11.4 | 12.3 | 27.8 | 26.5 | 28.3 | 44.6 |
| Week 6 | 18.2 | 24.6 | 44.4 | 49.0 | 49.1 | 55.4 |
| Week 12 | 15.9 | 29.8 | 37.0 | 40.8 | 50.9 | 57.1 |
| Week 18 | 13.6 | 26.3 | 38.9 | 44.9 | 39.6 | 46.4 |
| Week 24 | 13.6 | 28.1 | 27.8 | 42.9 | 54.7 | 53.6 |
| Week 30 | 18.2 | 21.1 | 35.2 | 28.6 | 41.5 | 46.4 |
| Week 36 | 11.4 | 15.8 | 33.3 | 36.7 | 32.1 | 42.9 |

## Reported Adverse Events

| | |
|---|---|
| Time Frame | [Not specified] |
| Additional Description | The Safety Population is defined as all randomized patients who received treatment and was used to analyze Serious Adverse Events and Adverse Events. |

Reporting Groups

| | Description |
|---|---|
| Placebo | Placebo (normal saline)injection on Day 1 into detrusor |
| BOTOX 50 U | botulinum toxin Type A 50 U injection on Day 1 into detrusor |

| | Description |
|---|---|
| BOTOX 100 U | botulinum toxin Type A 100 U injection on Day 1 into detrusor |
| BOTOX 150 U | botulinum toxin Type A 150 U injection on Day 1 into detrusor |
| BOTOX 200 U | botulinum toxin Type A 200 U injection on Day 1 into detrusor |
| BOTOX 300 U | botulinum toxin Type A 300 U injection on Day 1 into detrusor |

Serious Adverse Events

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Total | 5/ | 9/ | 5/ | 7/ | 4/ | 4/ |
| Cardiac disorders | | | | | | |
| Angina pectoris [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 1/50 (2%) | 0/52 (0%) | 0/55 (0%) |
| Atrial Fibrillation [A] * | 0/43 (0%) | 1/56 (1.79%) | 0/55 (0%) | 0/50 (0%) | 1/52 (1.92%) | 0/55 (0%) |
| Cardiac failure congestive [A] * | 0/43 (0%) | 0/56 (0%) | 1/55 (1.82%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Coronary artery disease [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 1/50 (2%) | 0/52 (0%) | 0/55 (0%) |
| Gastrointestinal disorders | | | | | | |
| Gastrointestinal haemorrhage [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 1/52 (1.92%) | 0/55 (0%) |
| Ileus [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 1/55 (1.82%) |
| Impaired gastric emptying [A] * | 0/43 (0%) | 1/56 (1.79%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Hepatobiliary disorders | | | | | | |
| Cholelithiasis [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 1/52 (1.92%) | 0/55 (0%) |
| Infections and infestations | | | | | | |
| Bacterial pyelonephritis [A] * | 0/43 (0%) | 1/56 (1.79%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Diverticulitis [A] * | 0/43 (0%) | 1/56 (1.79%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 1/55 (1.82%) |
| Herpes ophthalmic [A] * | 1/43 (2.33%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Urinary tract infection [A] * | 0/43 (0%) | 1/56 (1.79%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Injury, poisoning and procedural complications | | | | | | |
| Concussion [A] * | 1/43 (2.33%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Hip Fracture [A] * | 1/43 (2.33%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Skeletal injury [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 1/52 (1.92%) | 0/55 (0%) |
| Metabolism and nutrition disorders | | | | | | |
| Dehydration [A] * | 0/43 (0%) | 1/56 (1.79%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 1/55 (1.82%) |
| Diabetes mellitus [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 1/50 (2%) | 0/52 (0%) | 0/55 (0%) |
| Musculoskeletal and connective tissue disorders | | | | | | |
| Osteoarthritis [A] * | 0/43 (0%) | 0/56 (0%) | 2/55 (3.64%) | 1/50 (2%) | 0/52 (0%) | 0/55 (0%) |
| Osteoporotic fracture [A] * | 1/43 (2.33%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Polymyalgia rheumatica [A] * | 0/43 (0%) | 0/56 (0%) | 1/55 (1.82%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | | | | |
| Basal cell carcinoma [A] * | 1/43 (2.33%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Breast cancer [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 2/50 (4%) | 0/52 (0%) | 2/55 (3.64%) |
| Lung adenocarcinoma metastatic [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 1/50 (2%) | 0/52 (0%) | 0/55 (0%) |
| Lung neoplasm malignant [A] * | 0/43 (0%) | 1/56 (1.79%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Malignant melanoma [A] * | 0/43 (0%) | 0/56 (0%) | 1/55 (1.82%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Squamos cell carcinoma [A] * | 1/43 (2.33%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Nervous system disorders | | | | | | |
| Convulsion [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 1/55 (1.82%) |
| Headache [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 1/50 (2%) | 0/52 (0%) | 0/55 (0%) |
| Ischaemic stroke [A] * | 0/43 (0%) | 1/56 (1.79%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Normal pressure hydrocephalus [A] * | 1/43 (2.33%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Syncope [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 1/50 (2%) | 0/52 (0%) | 0/55 (0%) |
| Psychiatric disorders | | | | | | |
| Schizophrenia, undifferentiated type [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 1/52 (1.92%) | 0/55 (0%) |
| Renal and urinary disorders | | | | | | |
| Cystitis noninfective [A] * | 0/43 (0%) | 0/56 (0%) | 1/55 (1.82%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Urinary retention [A] * | 0/43 (0%) | 0/56 (0%) | 1/55 (1.82%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Reproductive system and breast disorders | | | | | | |
| Ovarian cyst [A] * | 0/43 (0%) | 1/56 (1.79%) | 0/55 (0%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Vascular disorders | | | | | | |
| Hypertension [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 0/50 (0%) | 1/52 (1.92%) | 0/55 (0%) |
| Hypotension [A] * | 0/43 (0%) | 0/56 (0%) | 0/55 (0%) | 1/50 (2%) | 0/52 (0%) | 0/55 (0%) |

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (11.0)

Other Adverse Events

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

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Total | 33/ | 44/ | 44/ | 39/ | 44/ | 46/ |
| Gastrointestinal disorders | | | | | | |
| Abdominal pain [A] * | 4/43 (9.3%) | 3/56 (5.36%) | 1/55 (1.82%) | 0/50 (0%) | 0/52 (0%) | 1/55 (1.82%) |
| Diarrhoea [A] * | 1/43 (2.33%) | 5/56 (8.93%) | 2/55 (3.64%) | 1/50 (2%) | 3/52 (5.77%) | 2/55 (3.64%) |
| Nausea [A] * | 4/43 (9.3%) | 1/56 (1.79%) | 4/55 (7.27%) | 0/50 (0%) | 2/52 (3.85%) | 1/55 (1.82%) |

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Infections and infestations | | | | | | |
| Bronchitis [A] * | 0/43 (0%) | 2/56 (3.57%) | 3/55 (5.45%) | 0/50 (0%) | 2/52 (3.85%) | 3/55 (5.45%) |
| Influenza [A] * | 0/43 (0%) | 1/56 (1.79%) | 3/55 (5.45%) | 3/50 (6%) | 5/52 (9.62%) | 1/55 (1.82%) |
| Lower respiratory tract infection [A] * | 0/43 (0%) | 1/56 (1.79%) | 3/55 (5.45%) | 2/50 (4%) | 0/52 (0%) | 1/55 (1.82%) |
| Nasopharyngitis [A] * | 1/43 (2.33%) | 1/56 (1.79%) | 6/55 (10.91%) | 1/50 (2%) | 2/52 (3.85%) | 2/55 (3.64%) |
| Sinusitis [A] * | 2/43 (4.65%) | 5/56 (8.93%) | 2/55 (3.64%) | 1/50 (2%) | 0/52 (0%) | 1/55 (1.82%) |
| Upper respiratory tract infection [A] * | 2/43 (4.65%) | 3/56 (5.36%) | 3/55 (5.45%) | 4/50 (8%) | 2/52 (3.85%) | 5/55 (9.09%) |
| Urinary tract infection [A] * | 7/43 (16.28%) | 19/56 (33.93%) | 20/55 (36.36%) | 22/50 (44%) | 25/52 (48.08%) | 19/55 (34.55%) |
| Investigations | | | | | | |
| Blood urine present [A] * | 3/43 (6.98%) | 1/56 (1.79%) | 1/55 (1.82%) | 0/50 (0%) | 0/52 (0%) | 1/55 (1.82%) |
| Residual urine volume [A] * | 0/43 (0%) | 3/56 (5.36%) | 1/55 (1.82%) | 3/50 (6%) | 4/52 (7.69%) | 1/55 (1.82%) |
| White blood cells urine positive [A] * | 2/43 (4.65%) | 1/56 (1.79%) | 4/55 (7.27%) | 1/50 (2%) | 3/52 (5.77%) | 2/55 (3.64%) |
| Musculoskeletal and connective tissue disorders | | | | | | |
| Arthralgia [A] * | 0/43 (0%) | 0/56 (0%) | 2/55 (3.64%) | 2/50 (4%) | 4/52 (7.69%) | 1/55 (1.82%) |
| Back pain [A] * | 5/43 (11.63%) | 1/56 (1.79%) | 3/55 (5.45%) | 1/50 (2%) | 0/52 (0%) | 3/55 (5.45%) |
| Pain in extremity [A] * | 2/43 (4.65%) | 0/56 (0%) | 3/55 (5.45%) | 1/50 (2%) | 0/52 (0%) | 3/55 (5.45%) |
| Nervous system disorders | | | | | | |
| Dizziness [A] * | 1/43 (2.33%) | 3/56 (5.36%) | 5/55 (9.09%) | 0/50 (0%) | 0/52 (0%) | 3/55 (5.45%) |
| Headache [A] * | 2/43 (4.65%) | 1/56 (1.79%) | 0/55 (0%) | 2/50 (4%) | 3/52 (5.77%) | 1/55 (1.82%) |
| Sciatica [A] * | 3/43 (6.98%) | 0/56 (0%) | 1/55 (1.82%) | 1/50 (2%) | 0/52 (0%) | 0/55 (0%) |
| Psychiatric disorders | | | | | | |
| Depression [A] * | 1/43 (2.33%) | 1/56 (1.79%) | 3/55 (5.45%) | 1/50 (2%) | 1/52 (1.92%) | 1/55 (1.82%) |

| | Placebo | BOTOX 50 U | BOTOX 100 U | BOTOX 150 U | BOTOX 200 U | BOTOX 300 U |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Renal and urinary disorders | | | | | | |
| Bladder pain [A] * | 1/43 (2.33%) | 1/56 (1.79%) | 0/55 (0%) | 4/50 (8%) | 1/52 (1.92%) | 2/55 (3.64%) |
| Dysuria [A] * | 5/43 (11.63%) | 7/56 (12.5%) | 1/55 (1.82%) | 4/50 (8%) | 6/52 (11.54%) | 1/55 (1.82%) |
| Haematuria [A] * | 6/43 (13.95%) | 5/56 (8.93%) | 0/55 (0%) | 2/50 (4%) | 1/52 (1.92%) | 0/55 (0%) |
| Pollakiuria [A] * | 0/43 (0%) | 4/56 (7.14%) | 1/55 (1.82%) | 1/50 (2%) | 0/52 (0%) | 2/55 (3.64%) |
| Renal cyst [A] * | 2/43 (4.65%) | 2/56 (3.57%) | 0/55 (0%) | 1/50 (2%) | 3/52 (5.77%) | 1/55 (1.82%) |
| Urinary retention [A] * | 1/43 (2.33%) | 5/56 (8.93%) | 10/55 (18.18%) | 14/50 (28%) | 12/52 (23.08%) | 14/55 (25.45%) |
| Reproductive system and breast disorders | | | | | | |
| Ovarian cyst [A] * | 0/43 (0%) | 3/56 (5.36%) | 2/55 (3.64%) | 0/50 (0%) | 0/52 (0%) | 0/55 (0%) |
| Respiratory, thoracic and mediastinal disorders | | | | | | |
| Cough [A] * | 0/43 (0%) | 0/56 (0%) | 3/55 (5.45%) | 1/50 (2%) | 1/52 (1.92%) | 1/55 (1.82%) |
| Skin and subcutaneous tissue disorders | | | | | | |
| Rash [A] * | 1/43 (2.33%) | 2/56 (3.57%) | 0/55 (0%) | 1/50 (2%) | 0/52 (0%) | 3/55 (5.45%) |
| Vascular disorders | | | | | | |
| Hypertension [A] * | 2/43 (4.65%) | 1/56 (1.79%) | 1/55 (1.82%) | 2/50 (4%) | 3/52 (5.77%) | 1/55 (1.82%) |

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (11.0)

## 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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