ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 12/04/2015

ClinicalTrials.gov ID: NCT00564681

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | 191622-090 |
| Brief Title: | Study to Evaluate Safety, Efficacy of Botulinum Toxin Type A in Patients With Cervical Dystonia |
| Official Title: | |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | December 2015 |
| Overall Status: | Completed |
| Study Start: | December 2007 |
| Primary Completion: | December 2008 [Actual] |
| Study Completion: | December 2009 [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: 723<br>Serial Number:<br>Has Expanded Access? No |
| Review Board: | Approval Status:<br>Board Name:<br>Board Affiliation:<br>Phone:<br>Email: |
| Data Monitoring?: | No |
| Plan to Share Data?: | |
| Oversight Authorities: | United States: Food and Drug Administration |

## Study Description

| | |
|---|---|
| Brief Summary: | Study is to investigate the use of the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) scale in a cervical dystonia population treated with botulinum toxin type A, and placebo. |
| Detailed Description: | |

## Conditions

| | |
|---|---|
| Conditions: | Cervical Dystonia |
| 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, Investigator) |
| Allocation: | Randomized |

Endpoint Classification: Safety/Efficacy Study

Enrollment: 242 [Actual]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Active Comparator: botulinum toxin Type A<br>Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments. | Biological/Vaccine: botulinum toxin type A<br>Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments.<br>Other Names:<br>• BOTOX® |
| Active Comparator: botulinum toxin Type A Formulation 2<br>Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments. | Biological/Vaccine: botulinum toxin type A Formulation 2<br>Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments. |
| Placebo (Normal Saline) / botulinum toxin Type A<br>Intramuscular injections of the assigned study medication into the affected muscles (placebo for treatment cycle 1 and botulinum toxin Type A for subsequent treatments). Maximum dose of 360 units. Subjects may receive up to three treatments. | Biological/Vaccine: botulinum toxin type A<br>Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments.<br>Other Names:<br>• BOTOX®<br>Drug: Normal Saline<br>Intramuscular injections of placebo (normal saline) into the affected muscles for treatment cycle 1. |
| Placebo (Normal Saline) / botulinum toxin Type A Formulation 2<br>Intramuscular injections of the assigned study medication into the affected muscles (placebo for treatment cycle 1 and botulinum toxin Type A Formulation 2 for subsequent treatments). Maximum dose of 360 units. Subjects may receive up to three treatments. | Biological/Vaccine: botulinum toxin type A Formulation 2<br>Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments.<br>Drug: Normal Saline<br>Intramuscular injections of placebo (normal saline) into the affected muscles for treatment cycle 1. |

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 18 Years

Maximum Age: 75 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Diagnosis of cervical dystonia

Exclusion Criteria:

- Current or previous botulinum toxin treatment of any type for any condition

## Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc.

Locations: United States, North Carolina
Winston-Salem, North Carolina, United States

Czech Republic
Prague, Czech Republic

Germany
Berlin, Germany

Hungary
Budapest, Hungary

India
Mumbai, India

Poland
Warsaw, Poland

Russian Federation
Moscow, Russian Federation

Serbia
Belgrade, Serbia

Singapore
Singapore, Singapore

Slovakia
Banska Bystrica, Slovakia

South Africa
Johannesburg, South Africa

Taiwan
Tainan, Taiwan

United Kingdom
Bristol, United Kingdom

Philippines
Manila, Philippines

Thailand
Bangkok, Thailand

Canada, Nova Scotia
Halifax, Nova Scotia, Canada

Slovakia
Spisska Nova, Slovakia

South Africa
Cape Town, South Africa

## References

Citations:

Links:

Study Data/Documents:

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# Study Results

## Participant Flow

Reporting Groups

| | Description |
|---|---|
| Botulinum Toxin Type A | Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments. |

| | Description |
|---|---|
| Botulinum Toxin Type A Formulation 2 | Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments. |
| Placebo (Normal Saline) / Botulinum Toxin Type A | Intramuscular injections of the assigned study medication into the affected muscles (placebo for treatment cycle 1 and botulinum toxin Type A for subsequent treatments). Maximum dose of 360 units. Subjects may receive up to three treatments. |
| Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 | Intramuscular injections of the assigned study medication into the affected muscles (placebo for treatment cycle 1 and botulinum toxin Type A Formulation 2 for subsequent treatments). Maximum dose of 360 units. Subjects may receive up to three treatments. |

Overall Study

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) / Botulinum Toxin Type A | Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 |
|---|---|---|---|---|
| Started | 117 | 61 | 43 | 21 |
| Completed | 106 | 58 | 40 | 19 |
| Not Completed | 11 | 3 | 3 | 2 |

## Baseline Characteristics

Reporting Groups

| | Description |
|---|---|
| Botulinum Toxin Type A | Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments. |
| Botulinum Toxin Type A Formulation 2 | Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments. |
| Placebo (Normal Saline) / Botulinum Toxin Type A | Intramuscular injections of the assigned study medication into the affected muscles (placebo for treatment cycle 1 and botulinum toxin Type A for subsequent treatments). Maximum dose of 360 units. Subjects may receive up to three treatments. |
| Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 | Intramuscular injections of the assigned study medication into the affected muscles (placebo for treatment cycle 1 and botulinum toxin Type A Formulation 2 for subsequent treatments). Maximum dose of 360 units. Subjects may receive up to three treatments. |

Baseline Measures

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) / Botulinum Toxin Type A | Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 | Total |
|---|---|---|---|---|---|
| Number of Participants | 117 | 61 | 43 | 21 | 242 |
| Age, Customized [units: Participants] | | | | | |
| <45 years | 38 | 22 | 13 | 11 | 84 |
| Between 45 and 65 years | 71 | 28 | 24 | 8 | 131 |
| >65 years | 8 | 11 | 6 | 2 | 27 |
| Gender, Male/Female [units: participants] | | | | | |
| Female | 81 | 43 | 32 | 13 | 169 |
| Male | 36 | 18 | 11 | 8 | 73 |

## Outcome Measures

1. Primary Outcome Measure:

| | |
|---|---|
| Measure Title | Change From Baseline in Observed Total Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) Score at Week 4 of Treatment Cycle 1 |
| Measure Description | Change from baseline in observed TWSTRS score at Week 4 of Treatment Cycle 1. The TWSTRS is an assessment scale used to measure the impact of cervical dystonia on patients. The score 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. A negative change from baseline represents improvement and a positive change from baseline indicates worsening. |
| Time Frame | Baseline, Week 4 |
| Safety Issue? | No |

Analysis Population Description

Intent-To-Treat: All enrolled patients

Reporting Groups

| | Description |
|---|---|
| Botulinum Toxin Type A | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |

| | Description |
|---|---|
| Botulinum Toxin Type A Formulation 2 | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |
| Placebo (Normal Saline) | Intramuscular injections into the affected muscles. Includes all patients who received placebo in Cycle 1. |

Measured Values

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) |
|---|---|---|---|
| Number of Participants Analyzed | 117 | 61 | 64 |
| Change From Baseline in Observed Total Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) Score at Week 4 of Treatment Cycle 1<br>[units: Scores on a Scale]<br>Mean (Standard Deviation) | | | |
| Baseline | 40.4 (9.14) | 41.5 (9.40) | 39.6 (9.52) |
| Change from Baseline at Week 4 | -10.3 (9.77) | -13.6 (10.20) | -5.6 (8.58) |

2. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Physician's Global Assessment of Response to Treatment at Week 4 of Treatment Cycle 1 |
| Measure Description | Physician’s global assessment of response to treatment at Week 4 of Treatment Cycle 1. Responses were measured on a 9-point scale of +4 to -4, with higher scores denoting improvement in cervical dystonia: +4 was 'Complete abolishment of signs and symptoms (100% improvement)', 0 represented 'No change', and -4 represented 'Very marked worsening (about 100% worse or greater)'. |
| Time Frame | Week 4 |
| Safety Issue? | No |

Analysis Population Description

Intent-to-Treat: All enrolled patients

Reporting Groups

| | Description |
|---|---|
| Botulinum Toxin Type A | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |
| Botulinum Toxin Type A Formulation 2 | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |

| | Description |
|---|---|
| Placebo (Normal Saline) | Intramuscular injections into the affected muscles. Includes all patients who received placebo in Cycle 1. |

Measured Values

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) |
|---|---|---|---|
| Number of Participants Analyzed | 117 | 61 | 64 |
| Physician's Global Assessment of Response to Treatment at Week 4 of Treatment Cycle 1<br>[units: Scores on a Scale]<br>Mean (Standard Deviation) | 1.3 (1.13) | 1.6 (1.04) | 0.8 (1.00) |

3. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Patient's Global Assessment of Response to Treatment at Week 4 of Treatment Cycle 1 |
| Measure Description | Patient’s global assessment of response to treatment at Week 4 of Treatment Cycle 1. Responses were measured on a 9-point scale of +4 to -4, with higher scores denoting improvement in cervical dystonia: +4 was 'Complete abolishment of signs and symptoms (100% improvement)', 0 represented 'No change', and -4 represented 'Very marked worsening (about 100% worse or greater)'. |
| Time Frame | Week 4 |
| Safety Issue? | No |

Analysis Population Description

Intent-to-Treat: All enrolled patients

Reporting Groups

| | Description |
|---|---|
| Botulinum Toxin Type A | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |
| Botulinum Toxin Type A Formulation 2 | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |
| Placebo (Normal Saline) | Intramuscular injections into the affected muscles. Includes all patients who received placebo in Cycle 1. |

Measured Values

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) |
|---|---|---|---|
| Number of Participants Analyzed | 117 | 61 | 64 |
| Patient's Global Assessment of Response to Treatment at Week 4 of Treatment Cycle 1<br>[units: Scores on a Scale]<br>Mean (Standard Deviation) | 1.3 (1.31) | 1.5 (1.07) | 0.6 (1.06) |

4. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Change From Baseline in Pain as Evaluated With the TWSTRS Pain Subscale at Week 4 of Treatment Cycle 1 |
| Measure Description | Change from baseline in pain as evaluated with the TWSTRS pain subscale at Week 4 of Treatment Cycle 1. The TWSTRS pain subscale scores range from 0 to 20 (0=no pain and 20=worst pain), based on severity of neck pain (0=no pain and 10=worst pain), the duration of pain (0=none and 5=most), and the degree of disability (0=none and 5=most). A negative number change from Baseline represents a decrease in pain (improvement). |
| Time Frame | Baseline, Week 4 |
| Safety Issue? | No |

Analysis Population Description

Intent-to-Treat: All enrolled patients

Reporting Groups

| | Description |
|---|---|
| Botulinum Toxin Type A | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |
| Botulinum Toxin Type A Formulation 2 | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |
| Placebo (Normal Saline) | Intramuscular injections into the affected muscles. Includes all patients who received placebo in Cycle 1. |

Measured Values

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) |
|---|---|---|---|
| Number of Participants Analyzed | 117 | 61 | 64 |
| Change From Baseline in Pain as Evaluated With the TWSTRS Pain Subscale at Week 4 of Treatment Cycle 1 | | | |

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) |
|---|---|---|---|
| [units: Scores on a Scale]<br>Mean (Standard Deviation) | | | |
| Baseline | 9.7 (4.04) | 10.0 (3.41) | 9.7 (4.13) |
| Change from Baseline at Week 4 | -2.8 (3.72) | -4.1 (4.15) | -1.3 (3.59) |

5. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Duration of Treatment Effect for Treatment Responders |
| Measure Description | Duration of Treatment Effect for Treatment Responders is defined as the number of days from the date of first treatment to the first visit after Week 4 of Treatment Cycle 1, at which the Total TWSTRS score reaches at least 90% of the baseline score. A treatment responder is defined as a patient who has at least a 30% reduction in Total TWSTRS score at Week 4 after the first treatment. The TWSTRS score measures the impact of cervical dystonia on patients (0=least symptoms and 85= worst symptoms). |
| Time Frame | Up to 6 Months |
| Safety Issue? | No |

Analysis Population Description

Intent-to-Treat: All enrolled patients

Reporting Groups

| | Description |
|---|---|
| Botulinum Toxin Type A | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |
| Botulinum Toxin Type A Formulation 2 | Intramuscular injections into the affected muscles. Maximum dose of 360 units. |
| Placebo (Normal Saline) | Intramuscular injections into the affected muscles. Includes all patients who received placebo in Cycle 1. |

Measured Values

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) |
|---|---|---|---|
| Number of Participants Analyzed | 117 | 61 | 64 |
| Duration of Treatment Effect for Treatment Responders<br>[units: Days]<br>Median (95% Confidence Interval) | 111.0 (97.00 to 119.00) | 99.0 (96.00 to 113.00) | 99.0 (92.00 to 109.00) |

## Reported Adverse Events

| | |
|---|---|
| Time Frame | [Not specified] |
| Additional Description | The safety population was used to calculate the number of participants at risk for serious adverse events (SAEs) and adverse events (AEs) and is the total number of patients that were randomized AND treated. SAEs and AEs are presented by randomized arm and not necessarily by treatment received. |

Reporting Groups

| | Description |
|---|---|
| Botulinum Toxin Type A | Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments. |
| Botulinum Toxin Type A Formulation 2 | Intramuscular injections into the affected muscles. Maximum dose of 360 units. Subjects may receive up to three treatments. |
| Placebo (Normal Saline) / Botulinum Toxin Type A | Intramuscular injections of the assigned study medication into the affected muscles (placebo for treatment cycle 1 and botulinum toxin Type A for subsequent treatments). Maximum dose of 360 units. Subjects may receive up to three treatments. |
| Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 | Intramuscular injections of the assigned study medication into the affected muscles (placebo for treatment cycle 1 and botulinum toxin Type A Formulation 2 for subsequent treatments). Maximum dose of 360 units. Subjects may receive up to three treatments. |

Serious Adverse Events

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) / Botulinum Toxin Type A | Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 |
|---|---|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 9/117 (7.69%) | 1/61 (1.64%) | 5/42 (11.9%) | 1/21 (4.76%) |
| Cardiac disorders | | | | |
| Myocardial infarction [A] † | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |
| Ear and labyrinth disorders | | | | |
| Vertigo positional [A] * | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) / Botulinum Toxin Type A | Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 |
|---|---|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) |
| Gastrointestinal disorders | | | | |
| Cholecystitis [A] † | 0/117 (0%) | 0/61 (0%) | 1/42 (2.38%) | 0/21 (0%) |
| Duodenal ulcer perforation [A] † | 0/117 (0%) | 0/61 (0%) | 1/42 (2.38%) | 0/21 (0%) |
| Dysphagia [A] * | 0/117 (0%) | 0/61 (0%) | 1/42 (2.38%) | 0/21 (0%) |
| Inguinal hernia [A] † | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |
| Umbilical hernia [A] † | 0/117 (0%) | 0/61 (0%) | 1/42 (2.38%) | 0/21 (0%) |
| Infections and infestations | | | | |
| Appendicitis [A] † | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |
| Injury, poisoning and procedural complications | | | | |
| Hip fracture [A] † | 0/117 (0%) | 0/61 (0%) | 1/42 (2.38%) | 0/21 (0%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | | |
| Adrenal adenoma [A] † | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |
| Breast cancer [A] † | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |
| Sarcoma [A] † | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |
| Nervous system disorders | | | | |
| Sciatica [A] * | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |
| Renal and urinary disorders | | | | |
| Renal colic [A] † | 0/117 (0%) | 1/61 (1.64%) | 0/42 (0%) | 0/21 (0%) |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Sinus disorder [A] † | 0/117 (0%) | 0/61 (0%) | 0/42 (0%) | 1/21 (4.76%) |
| Skin and subcutaneous tissue disorders | | | | |
| Dermatitis contact [A] † | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) / Botulinum Toxin Type A | Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 |
|---|---|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) |
| Surgical and medical procedures | | | | |
| Abortion induced [A] † | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 0/21 (0%) |

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA version 10.0

Other Adverse Events

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

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) / Botulinum Toxin Type A | Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 |
|---|---|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 83/117 (70.94%) | 41/61 (67.21%) | 31/42 (73.81%) | 16/21 (76.19%) |
| Gastrointestinal disorders | | | | |
| Dysphagia [A] * | 10/117 (8.55%) | 7/61 (11.48%) | 4/42 (9.52%) | 2/21 (9.52%) |
| Nausea [A] * | 6/117 (5.13%) | 2/61 (3.28%) | 1/42 (2.38%) | 2/21 (9.52%) |
| Vomiting [A] * | 1/117 (0.85%) | 0/61 (0%) | 0/42 (0%) | 3/21 (14.29%) |
| General disorders | | | | |
| Fatigue [A] * | 4/117 (3.42%) | 0/61 (0%) | 3/42 (7.14%) | 0/21 (0%) |
| Influenza-like illness [A] * | 2/117 (1.71%) | 2/61 (3.28%) | 3/42 (7.14%) | 0/21 (0%) |
| Injection site pain [A] * | 9/117 (7.69%) | 5/61 (8.2%) | 3/42 (7.14%) | 4/21 (19.05%) |
| Pyrexia [A] † | 1/117 (0.85%) | 1/61 (1.64%) | 3/42 (7.14%) | 1/21 (4.76%) |
| Infections and infestations | | | | |
| Influenza [A] † | 1/117 (0.85%) | 2/61 (3.28%) | 0/42 (0%) | 2/21 (9.52%) |
| Upper respiratory tract infection [A] † | 1/117 (0.85%) | 4/61 (6.56%) | 2/42 (4.76%) | 0/21 (0%) |

| | Botulinum Toxin Type A | Botulinum Toxin Type A Formulation 2 | Placebo (Normal Saline) / Botulinum Toxin Type A | Placebo (Normal Saline) / Botulinum Toxin Type A Formulation 2 |
|---|---|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) | Affected/At Risk (%) |
| Urinary tract infection [A] † | 1/117 (0.85%) | 1/61 (1.64%) | 0/42 (0%) | 2/21 (9.52%) |
| Metabolism and nutrition disorders | | | | |
| Hypercholesterolaemia [A] † | 2/117 (1.71%) | 0/61 (0%) | 0/42 (0%) | 2/21 (9.52%) |
| Musculoskeletal and connective tissue disorders | | | | |
| Back pain [A] * | 6/117 (5.13%) | 1/61 (1.64%) | 5/42 (11.9%) | 1/21 (4.76%) |
| Muscular weakness [A] * | 19/117 (16.24%) | 2/61 (3.28%) | 4/42 (9.52%) | 5/21 (23.81%) |
| Musculoskeletal pain [A] * | 6/117 (5.13%) | 3/61 (4.92%) | 2/42 (4.76%) | 3/21 (14.29%) |
| Musculoskeletal stiffness [A] * | 4/117 (3.42%) | 4/61 (6.56%) | 0/42 (0%) | 0/21 (0%) |
| Myalgia [A] * | 2/117 (1.71%) | 3/61 (4.92%) | 1/42 (2.38%) | 3/21 (14.29%) |
| Neck Pain [A] * | 20/117 (17.09%) | 10/61 (16.39%) | 5/42 (11.9%) | 1/21 (4.76%) |
| Nervous system disorders | | | | |
| Dizziness [A] * | 1/117 (0.85%) | 1/61 (1.64%) | 1/42 (2.38%) | 2/21 (9.52%) |
| Headache [A] * | 7/117 (5.98%) | 6/61 (9.84%) | 4/42 (9.52%) | 2/21 (9.52%) |
| Psychiatric disorders | | | | |
| Anxiety [A] * | 2/117 (1.71%) | 3/61 (4.92%) | 1/42 (2.38%) | 3/21 (14.29%) |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Nasopharyngitis [A] † | 7/117 (5.98%) | 4/61 (6.56%) | 2/42 (4.76%) | 1/21 (4.76%) |
| Vascular disorders | | | | |
| Hypertension [A] † | 8/117 (6.84%) | 3/61 (4.92%) | 1/42 (2.38%) | 0/21 (0%) |

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA version 10.0

## 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

Results Point of Contact:

Name/Official Title: Therapeutic Area Head,
Organization: Allergan, Inc
Phone: 714-246-4500
Email: clinicaltrials@allergan.com