ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 12/09/2011

ClinicalTrials.gov ID: NCT01271452

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | MAF/AGN/Facial/011 |
| Brief Title: | Safety and Efficacy of Two Types of Botulinum Toxin Type A For the Treatment of Glabellar Lines |
| Official Title: | |
| Secondary IDs: | 2010-021401-20 [EudraCT Number] |

## Study Status

| | |
|---|---|
| Record Verification: | December 2011 |
| Overall Status: | Completed |
| Study Start: | September 2010 |
| Primary Completion: | January 2011 [Actual] |
| Study Completion: | April 2011 [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?: | No |
| Review Board: | Approval Status: Approved<br>Approval Number: 10/15/2010<br>Board Name: Ethikkommission der Bayerischen<br>Board Affiliation: Bavarian Chamber of Physicians (BLÄK) - Central Institutional Review Board<br>Phone: (089) 4147-335<br>Email: ethikkommission@blaek.de |
| Data Monitoring?: | No |
| Plan to Share Data?: | |
| Oversight Authorities: | Germany: Ministry of Health |

## Study Description

| | |
|---|---|
| Brief Summary: | This study will evaluate the safety and efficacy of two different types of botulinum toxin type A for the treatment of glabellar frown lines. |
| Detailed Description: | |

## Conditions

| | |
|---|---|
| Conditions: | Glabellar Lines |
| 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, Caregiver, Investigator, Outcomes Assessor) |
| Allocation: | Randomized |
| Endpoint Classification: | Safety/Efficacy Study |
| Enrollment: | 224 [Actual] |

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Active Comparator: Vistabel®<br>botulinum toxin type A (Vistabel®) | Biological/Vaccine: botulinum toxin type A<br>20 units (total dose) botulinum toxin type A injected into glabellar region on Day 0<br>Other Names:<br>• Vistabel®<br>• BOTOX® Cosmetic |
| Active Comparator: Bocouture®<br>botulinum toxin type A (Bocouture®) | Biological/Vaccine: botulinum toxin type A<br>30 units (total dose) botulinum toxin type A injected into glabellar region on Day 0<br>Other Names:<br>• Bocouture® |

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 18 Years

Maximum Age: 65 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Moderate to severe glabellar frown lines

Exclusion Criteria:

- Diagnosis of myasthenia gravis or Eaton Lambert syndrome
- Aesthetic treatment with botulinum toxin within 6 months or planned treatment with botulinum toxin for any reason during the study
- Prior filler treatments, surgeries, insertion procedures in/to the glabellar region
- Facial cosmetic procedures in the glabellar area within 6 months
- Bleeding disorders or use of anticoagulants within 10 days
- History of facial nerve palsy

## Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc.

Locations: Germany
Munich, Bavaria, Germany

## References

Citations:

Links:

Study Data/Documents:

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# Study Results

## Participant Flow

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Overall Study

| | Vistabel® | Bocouture® |
|---|---|---|
| Started | 112 | 112 |
| Completed | 105 | 104 |
| Not Completed | 7 | 8 |

## Baseline Characteristics

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Baseline Measures

| | Vistabel® | Bocouture® | Total |
|---|---|---|---|
| Number of Participants | 112 | 112 | 224 |
| Age, Continuous<br>[units: years]<br>Mean (Standard Deviation) | 45.0 (10.80) | 45.4 (9.82) | 45.2 (10.30) |
| Gender, Male/Female<br>[units: participants] | | | |
| Female | 98 | 102 | 200 |
| Male | 14 | 10 | 24 |

## Outcome Measures

1. Primary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Subjects With a Treatment Response at Day 28 Based on the Injector's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the Facial Wrinkle Scale (FWS) |
| Measure Description | Number of subjects with a treatment response at Day 28 based on the injector’s assessment of the severity of glabellar lines at maximum contraction using the FWS. The FWS measures wrinkles on a scale from 0=none (best) to 3=severe (worst). Treatment response was defined as a 1 point or greater reduction from Day 0 in the FWS score at maximum contraction. |
| Time Frame | Day 28 |
| Safety Issue? | No |

Analysis Population Description

Intent-to-treat (ITT): all randomized subjects.

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Measured Values

| | Vistabel® | Bocouture® |
|---|---|---|
| Number of Participants Analyzed | 112 | 112 |
| Number of Subjects With a Treatment Response at Day 28 Based on the Injector's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the Facial Wrinkle Scale (FWS)<br>[units: Number of Subjects] | 108 | 106 |

2. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Subjects With a Treatment Response at Day 84 Based on the Injector's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS |
| Measure Description | Number of subjects with a treatment response at Day 84 based on the injector’s assessment of the severity of glabellar lines at maximum contraction using the FWS. The FWS measures wrinkles on a scale from 0=none (best) to 3=severe (worst). Treatment response was defined as a 1 point or greater reduction from Day 0 in the FWS score at maximum contraction. |
| Time Frame | Day 84 |
| Safety Issue? | No |

Analysis Population Description

ITT: all randomized subjects.

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Measured Values

| | Vistabel® | Bocouture® |
|---|---|---|
| Number of Participants Analyzed | 112 | 112 |
| Number of Subjects With a Treatment Response at Day 84 Based on the Injector's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS<br>[units: Number of Subjects] | 90 | 80 |

3. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Subjects With a Treatment Response at Day 98 Based on the Injector's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS |
| Measure Description | Number of subjects with a treatment response at Day 98 based on the injector’s assessment of the severity of glabellar lines at maximum contraction using the FWS. The FWS measures wrinkles on a scale from 0=none (best) to 3=severe (worst). Treatment response was defined as a 1 point or greater reduction from Day 0 in the FWS score at maximum contraction. |
| Time Frame | Day 98 |
| Safety Issue? | No |

Analysis Population Description

ITT: all randomized subjects.

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Measured Values

| | Vistabel® | Bocouture® |
|---|---|---|
| Number of Participants Analyzed | 112 | 112 |
| Number of Subjects With a Treatment Response at Day 98 Based on the Injector's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS<br>[units: Number of Subjects] | 76 | 70 |

4. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Subjects With a Treatment Response at Day 112 Based on the Injector's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS |
| Measure Description | Number of subjects with a treatment response at Day 112 based on the injector’s assessment of the severity of glabellar lines at maximum contraction using the FWS. The FWS measures wrinkles on a scale from 0=none (best) to 3=severe (worst). Treatment response was defined as a 1 point or greater reduction from Day 0 in the FWS score at maximum contraction. |
| Time Frame | Day 112 |
| Safety Issue? | No |

Analysis Population Description

ITT: all randomized subjects.

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Measured Values

| | Vistabel® | Bocouture® |
|---|---|---|
| Number of Participants Analyzed | 112 | 112 |
| Number of Subjects With a Treatment Response at Day 112 Based on the Injector's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS<br>[units: Number of Subjects] | 61 | 56 |

5. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Subjects With a Treatment Response at Day 28 Based on the Subject's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS |

| | |
|---|---|
| Measure Description | Number of subjects with a treatment response at Day 28 based on the subject’s assessment of the severity of glabellar lines at maximum contraction using the FWS. The FWS measures wrinkles on a scale from 0=none (best) to 3=severe (worst). Treatment response was defined as a 1 point or greater reduction from Day 0 in the FWS score at maximum contraction. |
| Time Frame | Day 28 |
| Safety Issue? | No |

Analysis Population Description

ITT: all randomized subjects.

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Measured Values

| | Vistabel® | Bocouture® |
|---|---|---|
| Number of Participants Analyzed | 112 | 112 |
| Number of Subjects With a Treatment Response at Day 28 Based on the Subject's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS<br>[units: Number of Subjects] | 108 | 102 |

6. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Subjects With a Treatment Response at Day 84 Based on the Subject's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS |
| Measure Description | Number of subjects with a treatment response at Day 84 based on the subject’s assessment of the severity of glabellar lines at maximum contraction using the FWS. The FWS measures wrinkles on a scale from 0=none (best) to 3=severe (worst). Treatment response was defined as a 1 point or greater reduction from Day 0 in the FWS score at maximum contraction. |
| Time Frame | Day 84 |
| Safety Issue? | No |

Analysis Population Description
ITT: all randomized subjects.

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Measured Values

| | Vistabel® | Bocouture® |
|---|---|---|
| Number of Participants Analyzed | 112 | 112 |
| Number of Subjects With a Treatment Response at Day 84 Based on the Subject's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS<br>[units: Number of Subjects] | 84 | 78 |

7. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Subjects With a Treatment Response at Day 98 Based on the Subject's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS |
| Measure Description | Number of subjects with a treatment response at Day 98 based on the subject’s assessment of the severity of glabellar lines at maximum contraction using the FWS. The FWS measures wrinkles on a scale from 0=none (best) to 3=severe (worst). Treatment response was defined as a 1 point or greater reduction from Day 0 in the FWS score at maximum contraction. |
| Time Frame | Day 98 |
| Safety Issue? | No |

Analysis Population Description
ITT: all randomized subjects.

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Measured Values

| | Vistabel® | Bocouture® |
|---|---|---|
| Number of Participants Analyzed | 112 | 112 |
| Number of Subjects With a Treatment Response at Day 98 Based on the Subject's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS<br>[units: Number of Subjects] | 73 | 68 |

8. Secondary Outcome Measure:

| | |
|---|---|
| Measure Title | Number of Subjects With a Treatment Response at Day 112 Based on the Subject's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS |
| Measure Description | Number of subjects with a treatment response at Day 112 based on the subject’s assessment of the severity of glabellar lines at maximum contraction using the FWS. The FWS measures wrinkles on a scale from 0=none (best) to 3=severe (worst). Treatment response was defined as a 1 point or greater reduction from Day 0 in the FWS score at maximum contraction. |
| Time Frame | Day 112 |
| Safety Issue? | No |

Analysis Population Description

ITT: all randomized subjects.

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Measured Values

| | Vistabel® | Bocouture® |
|---|---|---|
| Number of Participants Analyzed | 112 | 112 |
| Number of Subjects With a Treatment Response at Day 112 Based on the Subject's Assessment of the Severity of Glabellar Lines at Maximum Contraction Using the FWS<br>[units: Number of Subjects] | 61 | 54 |

## Reported Adverse Events

| | |
|---|---|
| Time Frame | [Not specified] |
| Additional Description | The Safety Population was used to analyze serious adverse events and adverse events and consisted of all randomised subjects who received at least one administration of study treatment (to at least one injection site). One subject in the Bocouture® treatment group was not included in the Safety Population. |

Reporting Groups

| | Description |
|---|---|
| Vistabel® | botulinum toxin type A (Vistabel®) |
| Bocouture® | botulinum toxin type A (Bocouture®) |

Serious Adverse Events

| | Vistabel® | Bocouture® |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 0/112 (0%) | 0/111 (0%) |

Other Adverse Events

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

| | Vistabel® | Bocouture® |
|---|---|---|
| | Affected/At Risk (%) | Affected/At Risk (%) |
| Total | 6/112 (5.36%) | 2/111 (1.8%) |
| Infections and infestations | | |
| Nasopharyngitis [A] * | 6/112 (5.36%) | 2/111 (1.8%) |

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (13.1)

## Limitations and Caveats

[Not specified]

## More Information

Certain Agreements:

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

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

A disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is at least 30 days from the time submitted to the sponsor for review. The sponsor can require changes to the communication and can extend the embargo

Results Point of Contact:

Name/Official Title: Vice President, Medical Affairs
Organization: Allergan, Inc.
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