ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 03/07/2012

ClinicalTrials.gov ID: NCT00777803

Study Identification

Unique Protocol ID:	MRZ 60201 GL_3002
Brief Title:	NT 201 (Xeomin®/Bocouture®) in Comparison With Clostridium Botulinum Toxin Type A in the Treatment of Glabellar Frown Lines (Head2Head)
Official Title:	A Prospective, Multicenter, Randomized, Rater- and Subject-Blind, Parallel Group Trial to Investigate the Non-Inferiority of NT 201, Free of Complexing Proteins, in Comparison With Clostridium Botulinum Toxin Type A in the Treatment of Glabellar Frown Lines
Secondary IDs:	2008-002713-40 [EudraCT Number]

Study Status

Record Verification:	March 2012
Overall Status:	Completed
Study Start:	November 2008
Primary Completion:	April 2009 [Actual]
Study Completion:	May 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Merz Pharmaceuticals GmbH
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: FF 69/2008 Board Name: Ethikkommission der Landesärztekammer Hessen Board Affiliation: Ethikkommission der Landesärztekammer Hessen Phone: +49/69/97672- Email: ethikkommission@laekh.de
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Germany: Federal Institute for Drugs and Medical Devices

Study Description

Brief Summary:	NT 201, also known as IncobotulinumtoxinA (Xeomin®/Bocouture®), is a Botulinum toxin type A preparation free of complexing proteins (150 kiloDalton). Injected into the muscle, NT201 causes a reversible local relaxation of the injected muscle. Botulinum toxin type A is used for aesthetic treatment of mimic wrinkles and in the therapy of neurologic diseases. This study will investigate the safety and efficacy (non-inferiority) of NT 201 in comparison with OnabotulinumtoxinA (Vistabel®) in the treatment of glabellar frown lines.
Detailed Description:	

Conditions

Conditions:	Glabellar Frown Lines
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2

Masking:	Double Blind (Subject, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	381 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: IncobotulinumtoxinA (Xeomin®/Bocouture®) IncobotulinumtoxinA (Xeomin®/Bocouture®), 24 units; mode of administration: intramuscular injection.	Drug: NT 201 (IncobotulinumtoxinA (Xeomin®/Bocouture®)) NT201, also known as IncobotulinumtoxinA (Xeomin®/Bocouture®), active ingredient: Clostridium botulinum neurotoxin type A free from complexing proteins, powder for solution for injection dose, 24 units; one injection session of solution, prepared by reconstitution of powder with 0.9% Sodium Chloride (NaCl). Of the 0.6 mL total injection volume, an aliquot of 0.15 mL was administered in the procerus muscle, aliquots of 0.125 mL were administered in the medial part of the both corrugator muscles and aliquots of 0.1 mL were administered in the middle part of both corrugator muscles. Other Names: • "Botulinum toxin type A (150 kiloDalton), free from complexing proteins"
Active Comparator: OnabotulinumtoxinA (Vistabel®) OnabotulinumtoxinA (Vistabel®), 24 units; mode of administration: intramuscular injection.	Drug: OnabotulinumtoxinA (Vistabel®) OnabotulinumtoxinA (Vistabel®), active ingredient: Clostridium botulinum neurotoxin type A, powder for solution for injection dose, 24 units; one injection session of solution, prepared by reconstitution of powder with 0.9% Sodium Chloride (NaCl). Of the 0.6 mL total injection volume, an aliquot of 0.15 mL was administered in the procerus muscle, aliquots of 0.125 mL were administered in the medial part of the both corrugator muscles and aliquots of 0.1 mL were administered in the middle part of both corrugator muscles. Other Names: • "BOTOX® Cosmetic" • "Botulinum toxin type A (900 kiloDalton)"

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 50 Years

Gender: Female

Accepts Healthy Volunteers?: No

Criteria: Main Inclusion Criteria:

• Moderate to severe glabellar frown lines at maximum frown (severity score of 2 or 3 on a 4-point facial wrinkle scale) as assessed by the investigator's rating: 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe'.

Main Exclusion Criteria:

- Marked facial asymmetry.
- Ptosis of eyelid and/or eyebrow.

Contacts/Locations

Study Officials: Medical Expert
Study Director
Merz Pharmaceuticals GmbH

Locations: Germany
Darmstadt, Germany

Austria
Vienna, Austria

Krems, Austria

Salzburg, Austria

Baden, Austria

United Kingdom
Suttion Coldfield, United Kingdom

Glasgow, United Kingdom

Manchester, United Kingdom

Winchester, United Kingdom

Germany
Frankfurt, Germany

Darmstadt, Germany

Wuppertal, Germany

Munich, Germany

Cologne, Germany

Bad Soden, Germany

Boeblingen, Germany

Korschenbroich, Germany

Ludwigshafen, Germany

References

Citations: [Study Results] Sattler G, Callander MJ, Grablowitz D, Walker T, Bee EK, Rzany B, Flynn TC, Carruthers A. Noninferiority of incobotulinumtoxinA, free from complexing proteins, compared with another botulinum toxin type A in the treatment of glabellar frown lines. Dermatol Surg. 2010 Dec;36 Suppl 4:2146-54. doi: 10.1111/j.1524-4725.2010.01706.x. PubMed 21134045

Links:

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	Subjects were randomized according to a ratio of 3:1 to be either treated with IncobotulinumtoxinA (Bocouture®) or with OnabotulinumtoxinA (Vistabel®).

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	

	Description
OnabotulinumtoxinA (Vistabel®)	

Overall Study

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Started	284	97
Completed	269	90
Not Completed	15	7
Lost to Follow-up	12	5
Adverse Event	1	0
Non-compliance	2	2

Baseline Characteristics

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Baseline Measures

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)	Total
Number of Participants	284	97	381
Age, Continuous [units: years] Mean (Standard Deviation)	41.6 (5.7)	42.0 (6.0)	41.7 (5.8)
Gender, Male/Female [units: participants]			
Female	284	97	381
Male	0	0	0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Responder by Independent Rater's Assessment at Maximum Frown at Week 4
Measure Description	The Outcome Measure Data Table describes the number of responders. A subject is a responder if at least 2 out of 3 independent rater identified a response. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 4 weeks thereafter at maximum frown. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	4 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	277	93
Responder by Independent Rater's Assessment at Maximum Frown at Week 4 [units: participants]	267	89

Statistical Analysis 1 for Responder by Independent Rater's Assessment at Maximum Frown at Week 4

Statistical Analysis Overview	Comparison Groups	IncobotulinumtoxinA (Xeomin®/Bocouture®), OnabotulinumtoxinA (Vistabel®)
	Comments	Null Hypothesis: Response rate of IncobotulinumtoxinA (Xeomin®/Bocouture®) minus the response rate of OnabotulinumtoxinA (Vistabel®) is lower or equal -15% (non-inferiority margin).
	Non-Inferiority or Equivalence Analysis?	Yes

	Comments	A two-sided 95% Newcombe confidence interval for proportions (paired data) was applied. The lower bound of the Newcombe-Wilson confidence interval of the difference in response rates between groups was compared to the non-inferiority margin of -15%.

Method of Estimation	Estimation Parameter	Other [difference of response rates]
	Estimated Value	0.7
	Confidence Interval	(2-Sided) 95% -3.2 to 7.1
	Estimation Comments	Difference of response rates = response rate in IncobotulinumtoxinA (Xeomin®/ Bocouture®) - response rate in OnabotulinumtoxinA (Vistabel®)

2. Secondary Outcome Measure:

Measure Title	Responder by Independent Rater's Assessment at Maximum Frown at Week 12
Measure Description	The Outcome Measure Data Table describes the number of responders. A subject is a responder if at least 2 out of 3 independent rater identified a response. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 12 weeks thereafter at maximum frown. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	12 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	268	88
Responder by Independent Rater's Assessment at Maximum Frown at Week 12 [units: participants]	222	73

3. Secondary Outcome Measure:

Measure Title	Responder by Independent Rater's Assessment at Rest at Week 4
Measure Description	The Outcome Measure Data Table describes the number of responders. A subject is a responder if at least 2 out of 3 independent rater identified a response. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 4 weeks thereafter at rest. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	4 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	277	92
Responder by Independent Rater's Assessment at Rest at Week 4 [units: participants]	115	37

4. Secondary Outcome Measure:

Measure Title	Responder by Independent Rater's Assessment at Rest at Week 12
Measure Description	The Outcome Measure Data Table describes the number of responders. A subject is a responder if at least 2 out of 3 independent rater identified a response. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 12 weeks thereafter at rest. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.

Time Frame	12 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	268	88
Responder by Independent Rater's Assessment at Rest at Week 12 [units: participants]	100	33

5. Secondary Outcome Measure:

Measure Title	Responder by Investigator's Assessment at Maximum Frown at Week 4
Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 4 weeks thereafter at maximum frown rated by the investigator. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	4 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	277	93
Responder by Investigator's Assessment at Maximum Frown at Week 4 [units: participants]	274	89

6. Secondary Outcome Measure:

Measure Title	Responder by Investigator's Assessment at Maximum Frown at Week 12
Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 12 weeks thereafter at maximum frown rated by the investigator. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	12 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	268	88

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Responder by Investigator's Assessment at Maximum Frown at Week 12 [units: participants]	220	76

7. Secondary Outcome Measure:

Measure Title	Responder by Investigator's Assessment at Rest at Week 4
Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 4 weeks thereafter at rest rated by the investigator. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	4 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	277	93
Responder by Investigator's Assessment at Rest at Week 4 [units: participants]	210	66

8. Secondary Outcome Measure:

Measure Title	Responder by Investigator's Assessment at Rest at Week 12

Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 12 weeks thereafter at rest rated by the investigator. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	12 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	268	88
Responder by Investigator's Assessment at Rest at Week 12 [units: participants]	166	51

9. Secondary Outcome Measure:

Measure Title	Responder by Patient's Assessment at Maximum Frown at Week 4
Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 4 weeks thereafter at maximum frown rated by the patient. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	4 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	277	93
Responder by Patient's Assessment at Maximum Frown at Week 4 [units: participants]	260	87

10. Secondary Outcome Measure:

Measure Title	Responder by Patient's Assessment at Maximum Frown at Week 12
Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 12 weeks thereafter at maximum frown rated by the patient. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	12 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	268	88

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Responder by Patient's Assessment at Maximum Frown at Week 12 [units: participants]	202	71

11. Secondary Outcome Measure:

Measure Title	Responder by Patient's Assessment at Rest at Week 4
Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 4 weeks thereafter at rest rated by the patient. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	4 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	277	93
Responder by Patient's Assessment at Rest at Week 4 [units: participants]	193	70

12. Secondary Outcome Measure:

Measure Title	Response by Patient's Assessment at Rest at Week 12

Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as an improvement of at least one point on a 4-point facial wrinkle scale from baseline to 12 weeks thereafter rated by the patient. The scale comprises the items 0 = 'none', 1 = 'mild', 2 = 'moderate', 3 = 'severe' wrinkles.
Time Frame	12 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing facial wrinkle scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	268	88
Response by Patient's Assessment at Rest at Week 12 [units: participants]	152	53

13. Secondary Outcome Measure:

Measure Title	Responder by Patient's Global Assessment at Week 4
Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as a score of at least +2 (moderate improvement) on a 9-point scale (range from +4 complete improvement to -4 very marked worsening) 4 weeks after treatment rated by the patient.
Time Frame	4 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	277	93
Responder by Patient's Global Assessment at Week 4 [units: participants]	259	86

14. Secondary Outcome Measure:

Measure Title	Responder by Patient's Global Assessment at Week 12
Measure Description	The Outcome Measure Data Table describes the number of responders. A response is defined as a score of at least +2 (moderate improvement) on a 9-point scale (range from +4 complete improvement to -4 very marked worsening) 12 weeks after treatment rated by the patient.
Time Frame	12 weeks after injection
Safety Issue?	No

Analysis Population Description

Analysis per protocol: All subjects who received study medication, for whom a facial wrinkle score at maximum frown was observed at baseline and who had no major protocol deviations. Missing scores were not imputed.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Measured Values

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Number of Participants Analyzed	268	88

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
Responder by Patient's Global Assessment at Week 12 [units: participants]	229	75

Reported Adverse Events

Time Frame	All SAEs/AEs up to 12 weeks after injection.
Additional Description	The table of "Other Adverse Events" includes all non-serious AEs. The investigator asked the patient for AEs systematically at each visit.

Reporting Groups

	Description
IncobotulinumtoxinA (Xeomin®/ Bocouture®)	
OnabotulinumtoxinA (Vistabel®)	

Serious Adverse Events

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/284 (0.35%)	1/97 (1.03%)
Infections and infestations		
Encephalitis viral [A] †	0/284 (0%)	1/97 (1.03%)
Injury, poisoning and procedural complications		
Joint injury [A] †	1/284 (0.35%)	0/97 (0%)
Tibia fracture [A] †	1/284 (0.35%)	0/97 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	IncobotulinumtoxinA (Xeomin®/Bocouture®)	OnabotulinumtoxinA (Vistabel®)
	Affected/At Risk (%)	Affected/At Risk (%)
Total	22/284 (7.75%)	12/97 (12.37%)
Infections and infestations		
Gastrointestinal infection [A] †	1/284 (0.35%)	2/97 (2.06%)
Nasopharyngitis [A] †	11/284 (3.87%)	4/97 (4.12%)
Nervous system disorders		
Headache [A] †	12/284 (4.23%)	7/97 (7.22%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 12.0

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.

No results to be published without written agreement by sponsor; manuscripts to be sent to sponsor at least 6 wks before submission. Sponsor to give written opinion within 30 d. Sponsor is entitled to exert influence on the contents of publications, to postpone publications up to 36 months after end of the study, and to name co-authors. In case of justified doubts of sponsor, the INVESTIGATOR will consider these doubts in the publication as long as the scientific neutrality is not affected.

Results Point of Contact:

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