ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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Study Identification

Unique Protocol ID:	MRZ 60201-0410
Brief Title:	IncobotulinumtoxinA (Xeomin) Versus Placebo in the Treatment of Post-stroke Spasticity of the Upper Limb
Official Title:	Prospective, Double-blind, Placebo-controlled, Randomized, Multi-center Trial With an Open-label Extension Period to Investigate the Efficacy and Safety of incobotulinumtoxinA (Xeomin) in the Treatment of Post-stroke Spasticity of the Upper Limb
Secondary IDs:	

Study Status

Record Verification:	November 2010
Overall Status:	Completed
Study Start:	June 2006
Primary Completion:	November 2006 [Actual]
Study Completion:	May 2008 [Actual]

Sponsor/Collaborators

Sponsor:	Merz Pharmaceuticals GmbH
Responsible Party:	
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 142/05 MEK 30 Board Name: The Ethics Committee of the Faculty Hospital Olomouc and Medical Faculty UP in Olomouc Board Affiliation: The Ethics Committee of the Faculty Hospital Olomouc and Medical Faculty UP in Olomouc Phone: +420-588443381 Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Czech Republic: State Institute for Drug Control Hungary: National Institute of Pharmacy Poland: Office for Registration of Medicinal Products, Medicinal Devices and Biocides

Study Description

Brief Summary:	IncobotulinumtoxinA (Xeomin) is a botulinum toxin type A preparation free from complexing proteins, i.e. free from proteins other than the active toxin. Injected into the muscle, incobotulinumtoxinA (Xeomin) causes local weakening. Botulinum toxin type A is widely used for treatment of various neurological conditions. This study will investigate the efficacy and safety of incobotulinumtoxinA (Xeomin) in the treatment of post-stroke spasticity of the upper limb.
Detailed Description:	

Conditions

Conditions:	Post-stroke Upper Limb Spasticity
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, Caregiver, Investigator, Outcomes Assessor)

Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	148 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: IncobotulinumtoxinA (Xeomin) incobotulinumtoxinA (Xeomin, also known as "NT 201" or "Botulinum toxin type A (150 kiloDalton), free from complexing proteins") (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% Sodium Chloride (NaCl), up to five injections in the Open-Label Extension Period, up to 400 units at each injection visit; Mode of administration: intramuscular injection	Drug: IncobotulinumtoxinA (Xeomin) incobotulinumtoxinA (Xeomin, also known as "NT 201" or "Botulinum toxin type A (150 kiloDalton), free from complexing proteins") (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% Sodium Chloride (NaCl), up to five injections in the Open-Label Extension Period, up to 400 units at each injection visit; Mode of administration: intramuscular injection
Placebo Comparator: Placebo	Drug: Placebo Placebo

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Main Inclusion Criteria:

- Female or male patients ≥ 18 years
- ≥ 6 months since the last stroke, diagnosed by an appropriate health care professional (e.g., neurologist)
- Focal spasticity with ≥ 2 points on the Ashworth Scale in the wrist flexors with clinical pattern Flexed Wrist
- Focal spasticity with ≥ 2 points on the Ashworth Scale in the fingers flexors with clinical pattern Clenched Fist
- For pre-treated patients only: source documentation of the most recent injection session with Botulinum Toxin and sufficient therapeutic response for Flexed Wrist and Clenched Fist
- For pre-treated patients only: the most recent injection with Botulinum Toxin must have been maximal 50 Units BOTOX® or 200 Units Dysport® or 2000 Units Neurobloc® (type B preparation) per each of these flexors: carpi ulnaris, digitorum superficialis, digitorum profundus

- For pre-treated patients only: the most recent injection with Botulinum Toxin must have been maximal 60 Units BOTOX® or 240 Units Dysport® or 2400 Units Neurobloc® (type B preparation) for flexor carpi radialis

Main Exclusion Criteria:

- Spasticity of any other origin than stroke
- Previous treatment with Botulinum Toxin of any serotype and for any body region within the 4 months prior to Screening (Visit 1, Day -7)
- Planned concomitant treatment with Botulinum Toxin of any serotype and for any body region
- Previous or planned treatment with phenol- or alcohol-injection in the target limb
- Previous surgical treatment of spasticity in the target muscle(s)
- Fixed contracture, defined as severe restriction of the range of joint movement on passive stretch
- Severe atrophy of the target limb muscles

Contacts/Locations

Study Officials: Merz Pharmaceuticals
Study Chair
Merz Pharmaceuticals GmbH

Merz Pharmaceuticals
Study Chair
Merz Pharmaceuticals GmbH

Locations: Czech Republic
Czech Republic, Czech Republic

Poland
Poland, Poland

Hungary
Hungary, Hungary

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Main Period

	incobotulinumtoxinA (Xeomin)	Placebo
Started	73	75
Completed	71	74
Not Completed	2	1
Adverse Event	1	1
Consent Withdrawn	1	0

Open-Label Extension Period

	incobotulinumtoxinA (Xeomin)	Placebo
Started	145	0 [1]
Completed	120	0
Not Completed	25	0
Withdrawal Criteria Occurred	1	0
Lack of Efficacy	6	0
Adverse Event	5	0
Consent withdrawn	10	0
Physician Decision	3	0

[1] In the Open-Label Extension Period no placebo treatment arm was given.

Baseline Characteristics

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Baseline Measures

	incobotulinumtoxinA (Xeomin)	Placebo	Total
Number of Participants	73	75	148
Age, Continuous [units: years] Mean (Standard Deviation)	58.1 (10.2)	53.3 (13.3)	55.6 (12.1)
Gender, Male/Female [units: participants]			
Female	28	25	53
Male	45	50	95

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Reduction of at Least 1 Point at Week 4 Compared to Baseline in Ashworth Score in Wrist Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were not imputed

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Number of Participants With Reduction of at Least 1 Point at Week 4 Compared to Baseline in Ashworth Score in Wrist Flexors [units: Participants]	50	28

Statistical Analysis 1 for Number of Participants With Reduction of at Least 1 Point at Week 4 Compared to Baseline in Ashworth Score in Wrist Flexors

Statistical Analysis Overview	Comparison Groups	incobotulinumtoxinA (Xeomin), Placebo
	Comments	The null hypothesis was equality of the chance (OR = 1) for a clinically relevant treatment effect between incobotulinumtoxinA (Xeomin) and placebo at Week 4 for wrist flexors. Responders were defined as subjects with an improvement of at least 1 point in the Ashworth score compared with Baseline. The dependent variable was the response to treatment, the independent variables were treatment, Ashworth score at the Baseline Visit, pre-treated patient status, gender, age, BMI, and pooled sites.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	[Not specified]
	Method	Regression, Logistic
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	3.97

	Confidence Interval	(2-Sided) 95% 1.90 to 8.30
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.49
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Responders at Week 4 Based on a Responder Definition of at Least 2 Points Improvement From Baseline in the Ashworth Score for Wrist Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by worst case, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Responders at Week 4 Based on a Responder Definition of at Least 2 Points Improvement From Baseline in the Ashworth Score for Wrist Flexors [units: Participants]	14	3

3. Secondary Outcome Measure:

Measure Title	Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Wrist Flexors at All Other Post Baseline Visits
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2, Week 8, Week 12, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by worst case, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	73
Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Wrist Flexors at All Other Post Baseline Visits [units: Participants]		
Week 2	45	22
Week 8	49	22
Week 12	31	18

	incobotulinumtoxinA (Xeomin)	Placebo
Final Visit	29	14

4. Secondary Outcome Measure:

Measure Title	Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Treated Elbow Flexors at All Post Baseline Visits
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2, Week 4, Week 8, Week 12, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by worst case, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	54	55
Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Treated Elbow Flexors at All Post Baseline Visits [units: Participants]		
Week 2	32	15

	incobotulinumtoxinA (Xeomin)	Placebo
Week 4	34	21
Week 8	27	22
Week 12	23	16
Final Visit	21	14

5. Secondary Outcome Measure:

Measure Title	Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Treated Forearm Pronators at All Post Baseline Visits
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2, Week 4, Week 8, Week 12, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by worst case, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	35	38

	incobotulinumtoxinA (Xeomin)	Placebo
Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Treated Forearm Pronators at All Post Baseline Visits [units: Participants]		
Week 2	16	10
Week 4	19	12
Week 8	18	11
Week 12	12	11
Final Visit	10	9

6. Secondary Outcome Measure:

Measure Title	Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Treated Finger Flexors at All Post Baseline Visits
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2, Week 4, Week 8, Week 12, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by worst case, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Treated Finger Flexors at All Post Baseline Visits [units: Participants]		
Week 2	50	22
Week 4	50	27
Week 8	44	27
Week 12	35	23
Final Visit	28	17

7. Secondary Outcome Measure:

Measure Title	Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Treated Thumb Flexors at All Post Baseline Visits
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2, Week 4, Week 8, Week 12, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by worst case, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection

	Description
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	26	31
Responders Based on a Responder Definition of at Least 1 Point Improvement From Baseline in the Ashworth Score for Treated Thumb Flexors at All Post Baseline Visits [units: Participants]		
Week 2	16	8
Week 4	17	11
Week 8	14	14
Week 12	14	10
Final Visit	11	10

8. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in Ashworth Scale Score for Treated Elbow Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	54	55
Change From Baseline to Week 2 in Ashworth Scale Score for Treated Elbow Flexors [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	5	0
Change of "-1" points	27	15
Change of "0" points	22	39
Change of "+1" points	0	1

9. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in Ashworth Scale Score for Treated Elbow Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	54	55
Change From Baseline to Week 4 in Ashworth Scale Score for Treated Elbow Flexors [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	5	1
Change of "-1" points	29	20
Change of "0" points	20	32
Change of "+1" points	0	2

10. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in Ashworth Scale Score for Treated Elbow Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	54	55
Change From Baseline to Week 8 in Ashworth Scale Score for Treated Elbow Flexors [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	6	2
Change of "-1" points	20	20
Change of "0" points	26	31
Change of "+1" points	0	2
Missing	1	0

11. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in Ashworth Scale Score for Treated Elbow Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	54	55
Change From Baseline to Week 12 in Ashworth Scale Score for Treated Elbow Flexors [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	5	0
Change of "-1" points	18	16
Change of "0" points	31	36
Change of "+1" points	0	2
Missing	0	1

12. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in Ashworth Scale Score for Treated Elbow Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	54	55
Change From Baseline to Final Visit in Ashworth Scale Score for Treated Elbow Flexors [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	2	0
Change of "-1" points	19	14
Change of "0" points	32	37
Change of "+1" points	1	3
Missing	0	1

13. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in Ashworth Scale Score for Treated Forearm Pronators
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	35	38
Change From Baseline to Week 2 in Ashworth Scale Score for Treated Forearm Pronators [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	3	0
Change of "-1" points	13	10
Change of "0" points	18	27
Change of "+1" points	1	1

14. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in Ashworth Scale Score for Treated Forearm Pronators
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	35	38
Change From Baseline to Week 4 in Ashworth Scale Score for Treated Forearm Pronators [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	2	0
Change of "-1" points	16	12
Change of "0" points	16	24
Change of "+1" points	0	1
Missing	0	1

15. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in Ashworth Scale Score for Treated Forearm Pronators
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	35	38
Change From Baseline to Week 8 in Ashworth Scale Score for Treated Forearm Pronators [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	2	0
Change of "-1" points	15	11
Change of "0" points	16	25
Change of "+1" points	1	1
Missing	0	1

16. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in Ashworth Scale Score for Treated Forearm Pronators
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 12

Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	35	38
Change From Baseline to Week 12 in Ashworth Scale Score for Treated Forearm Pronators [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	2	0
Change of "-1" points	10	11
Change of "0" points	21	20
Change of "+1" points	1	5
Missing	1	2

17. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in Ashworth Scale Score for Treated Forearm Pronators
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.

Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	35	38
Change From Baseline to Final Visit in Ashworth Scale Score for Treated Forearm Pronators [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	1	1
Change of "-1" points	9	8
Change of "0" points	22	21
Change of "+1" points	2	6
Missing	1	2

18. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in Ashworth Scale Score for Wrist Flexors

Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	73
Change From Baseline to Week 2 in Ashworth Scale Score for Wrist Flexors [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	11	2
Change of "-1" points	33	20
Change of "0" points	27	51
Change of "+1" points	1	0

19. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in Ashworth Scale Score for Wrist Flexors

Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	73
Change From Baseline to Week 4 in Ashworth Scale Score for Wrist Flexors [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	13	3
Change of "-1" points	36	25
Change of "0" points	22	41
Change of "+1" points	1	3
Missing	0	1

20. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in Ashworth Scale Score for Wrist Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	73
Change From Baseline to Week 8 in Ashworth Scale Score for Wrist Flexors [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	13	4
Change of "-1" points	35	18
Change of "0" points	21	47
Change of "+1" points	2	3
Missing	1	1

21. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in Ashworth Scale Score for Wrist Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	73
Change From Baseline to Week 12 in Ashworth Scale Score for Wrist Flexors [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	9	2
Change of "-1" points	21	16
Change of "0" points	38	47
Change of "+1" points	2	6
Missing	2	2

22. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in Ashworth Scale Score for Wrist Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	73
Change From Baseline to Final Visit in Ashworth Scale Score for Wrist Flexors [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	2	0
Change of "-1" points	27	14
Change of "0" points	39	50
Change of "+1" points	4	7
Missing	1	2

23. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in Ashworth Scale Score for Finger Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 2 in Ashworth Scale Score for Finger Flexors [units: Participants]		
Change of "-3" points	4	0
Change of "-2" points	8	2
Change of "-1" points	38	20
Change of "0" points	21	50
Change of "+1" points	2	3

24. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in Ashworth Scale Score for Finger Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in Ashworth Scale Score for Finger Flexors [units: Participants]		
Change of "-3" points	5	0
Change of "-2" points	15	5
Change of "-1" points	30	22
Change of "0" points	22	44
Change of "+1" points	1	3
Missing	0	1

25. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in Ashworth Scale Score for Finger Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 8 in Ashworth Scale Score for Finger Flexors [units: Participants]		
Change of "-3" points	2	0
Change of "-2" points	18	3
Change of "-1" points	24	24
Change of "0" points	27	43
Change of "+1" points	1	4

	incobotulinumtoxinA (Xeomin)	Placebo
Missing	1	1

26. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in Ashworth Scale Score for Finger Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in Ashworth Scale Score for Finger Flexors [units: Participants]		
Change of "-3" points	2	0
Change of "-2" points	9	2
Change of "-1" points	24	21

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "0" points	33	45
Change of "+1" points	3	5
Missing	2	2

27. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in Ashworth Scale Score for Finger Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in Ashworth Scale Score for Finger Flexors [units: Participants]		
Change of "-3" points	0	0

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "-2" points	2	1
Change of "-1" points	26	16
Change of "0" points	39	51
Change of "+1" points	5	5
Missing	1	2

28. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in Ashworth Scale Score for Treated Thumb Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	26	31
Change From Baseline to Week 2 in Ashworth Scale Score for Treated Thumb Flexors		

	incobotulinumtoxinA (Xeomin)	Placebo
[units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	3	1
Change of "-1" points	13	7
Change of "0" points	10	22
Change of "+1" points	0	1

29. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in Ashworth Scale Score for Treated Thumb Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	26	31

	incobotulinumtoxinA (Xeomin)	Placebo
Change From Baseline to Week 4 in Ashworth Scale Score for Treated Thumb Flexors [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	6	2
Change of "-1" points	11	9
Change of "0" points	9	18
Change of "+1" points	0	1
Missing	0	1

30. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in Ashworth Scale Score for Treated Thumb Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	26	31
Change From Baseline to Week 8 in Ashworth Scale Score for Treated Thumb Flexors [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	6	2
Change of "-1" points	8	12
Change of "0" points	11	15
Change of "+1" points	1	0
Change of "+2" points	0	1
Missing	0	1

31. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in Ashworth Scale Score for Treated Thumb Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection

	Description
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	26	31
Change From Baseline to Week 12 in Ashworth Scale Score for Treated Thumb Flexors [units: Participants]		
Change of "-3" points	0	1
Change of "-2" points	4	1
Change of "-1" points	10	8
Change of "0" points	11	14
Change of "+1" points	0	4
Change of "+2" points	0	1
Missing	1	2

32. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in Ashworth Scale Score for Treated Thumb Flexors
Measure Description	The Ashworth Scale is a well known and commonly used scale in clinical trials with spasticity. It was considered to be the best clinical tool for measuring resistance to movement. It was used to categorize the severity of spasticity by judging resistance to passive movement. It is a 5-point scale that ranges from 0 (=no increase in tone) to 4 (=limb rigid in flexion or extension). Subjects with a reduction of one point were defined as responder for the aim of the primary efficacy analysis.
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	26	31
Change From Baseline to Final Visit in Ashworth Scale Score for Treated Thumb Flexors [units: Participants]		
Change of "-3" points	0	1
Change of "-2" points	2	0
Change of "-1" points	9	9
Change of "0" points	13	14
Change of "+1" points	1	4
Change of "+2" points	0	1
Missing	1	2

33. Secondary Outcome Measure:

Measure Title	Time to Onset of Treatment Effect
Measure Description	Starting with the visit 2 weeks after baseline injection the subject was asked if he/she experienced an treatment effect and if "yes": when. If the subject did not experience an treatment effect he/she was asked again at each of the following visits (at week 4, 8, and 12) of the Main Period until the answer was "yes" or until the final visit of the Main Period was performed. For subjects without any treatment effect the time to onset of effect was censored at the last visit of the Main Period.
Time Frame	Period starting at Visit 2 (baseline injection) of the Main Period up to onset of treatment effect
Safety Issue?	No

Analysis Population Description

Results for placebo patients were not displayed because the upper limit of the confidence interval was not estimable (this can not be entered because a numeric entry is expected). The results of this analysis are therefore given as "Onset of Treatment Effect [classified]" under "Other Pre-specified Outcome".

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	0
Time to Onset of Treatment Effect [units: Days] Median (95% Confidence Interval)	4.0 (3.0 to 7.0)	

34. Secondary Outcome Measure:

Measure Title	Time to Waning of Treatment Effect
Measure Description	Subject who reported an onset of treatment effect were asked at each visit/telephone contact starting at week 4 at earliest if he/she felt that there was a waning of the treatment effect. The same question was asked at each of the following telephone contacts and visits (up to the Final Visit of the Main Period) if the answer at the respective previous visit was “no”. If the patient answered with “yes” he/she will be asked at which week after the injection (= the time span in weeks) the waning of effect occurred. For all subjects without an onset of treatment effect the waning was set to zero.
Time Frame	Defined as time (weeks) from Visit 2 (injection session at Baseline, Day 0) to the subjective estimation of the waning of the effect
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Time to Waning of Treatment Effect [units: Weeks] Median (95% Confidence Interval)	10.0 (9.0 to 11.0)	10.0 (10.0 to 11.0)

35. Secondary Outcome Measure:

Measure Title	Duration of Treatment Effect
Measure Description	The duration of treatment effect is defined as the time period from the day of injection until the time point of a need for a new injection agreed by the patient and the investigator. For subjects without any treatment effect the duration of effect was set to zero.
Time Frame	Period from the day of injection until the time point of a need for a new injection agreed by the patient and the investigator
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Duration of Treatment Effect [units: Days] Median (95% Confidence Interval)	87.0 (86.0 to 94.0)	84.0 (0.0 to 84.0)

36. Secondary Outcome Measure:

Measure Title	Investigator's Global Assessment of Efficacy
Measure Description	The Investigator's Global Assessment of Efficacy is a subjective estimation assessed on a 4-point Likert scale with the items 1=very good, 2=good, 3=moderate, and 4=poor.
Time Frame	Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Investigator's Global Assessment of Efficacy [units: Participants]		
Very good	11	2
Good	32	24
Moderate	14	12

	incobotulinumtoxinA (Xeomin)	Placebo
Poor	15	35
Missing	1	2

37. Secondary Outcome Measure:

Measure Title	Patient's Global Assessment of Efficacy
Measure Description	The Patient's Global Assessment of Efficacy is a subjective estimation assessed on a 4-point Likert scale with the items 1=very good, 2=good, 3=moderate, and 4=poor.
Time Frame	Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Patient's Global Assessment of Efficacy [units: Participants]		
Very good	7	2
Good	41	21
Moderate	9	17
Poor	15	33
Missing	1	2

38. Secondary Outcome Measure:

Measure Title	Carer's Global Assessment of Efficacy
Measure Description	The Carer's Global Assessment of Efficacy is a subjective estimation assessed on a 4-point Likert scale with the items 1=very good, 2=good, 3=moderate, and 4=poor.
Time Frame	Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Carer's Global Assessment of Efficacy [units: Participants]		
Very good	8	2
Good	21	17
Moderate	9	10
Poor	8	24
No carer	26	19
Missing	1	3

39. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in the Disability Assessment Scale for the Principal Therapeutic Target
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 2 in the Disability Assessment Scale for the Principal Therapeutic Target [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	7	1
Change of "-1" points	21	8
Change of "0" points	43	66
Change of "+1" points	2	0
Change of "+2" points	0	0

40. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Disability Assessment Scale for the Principal Therapeutic Target
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Disability Assessment Scale for the Principal Therapeutic Target [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	12	1
Change of "-1" points	21	15
Change of "0" points	40	57
Change of "+1" points	1	1
Change of "+2" points	0	0
Missing	0	1

41. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in the Disability Assessment Scale for the Principal Therapeutic Target
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 8 in the Disability Assessment Scale for the Principal Therapeutic Target [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	6	1
Change of "-1" points	26	15
Change of "0" points	37	57
Change of "+1" points	2	1
Change of "+2" points	0	0
Missing	2	1

42. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Disability Assessment Scale for the Principal Therapeutic Target
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in the Disability Assessment Scale for the Principal Therapeutic Target [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	3	2
Change of "-1" points	24	10
Change of "0" points	42	58
Change of "+1" points	2	3
Change of "+2" points	0	0
Missing	2	2

43. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Disability Assessment Scale for the Principal Therapeutic Target
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Disability Assessment Scale for the Principal Therapeutic Target [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	2	1
Change of "-1" points	20	14
Change of "0" points	47	55
Change of "+1" points	2	3
Change of "+2" points	1	0

	incobotulinumtoxinA (Xeomin)	Placebo
Missing	2	2

44. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in the Disability Assessment Scale for Domain "Hygiene"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 2 in the Disability Assessment Scale for Domain "Hygiene" [units: Participants]		
Change of "-3" points	2	0
Change of "-2" points	6	1
Change of "-1" points	12	7
Change of "0" points	52	66
Change of "+1" points	1	1

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "+2" points	0	0

45. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Disability Assessment Scale for Domain "Hygiene"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Disability Assessment Scale for Domain "Hygiene" [units: Participants]		
Change of "-3" points	3	0
Change of "-2" points	5	1
Change of "-1" points	14	11
Change of "0" points	48	59
Change of "+1" points	3	3

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "+2" points	0	0
Missing	0	1

46. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in the Disability Assessment Scale for Domain "Hygiene"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 8 in the Disability Assessment Scale for Domain "Hygiene" [units: Participants]		
Change of "-3" points	2	0
Change of "-2" points	6	1
Change of "-1" points	16	12
Change of "0" points	44	58

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "+1" points	3	3
Change of "+2" points	0	0
Missing	2	1

47. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Disability Assessment Scale for Domain "Hygiene"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in the Disability Assessment Scale for Domain "Hygiene" [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	4	1
Change of "-1" points	11	12

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "0" points	50	53
Change of "+1" points	4	7
Change of "+2" points	1	0
Missing	2	2

48. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Disability Assessment Scale for Domain "Hygiene"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Disability Assessment Scale for Domain "Hygiene" [units: Participants]		
Change of "-3" points	1	1
Change of "-2" points	2	1

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "-1" points	10	9
Change of "0" points	50	53
Change of "+1" points	6	9
Change of "+2" points	2	0
Missing	2	2

49. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in the Disability Assessment Scale for Domain "Dressing"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 2 in the Disability Assessment Scale for Domain "Dressing" [units: Participants]		
Change of "-3" points	1	0

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "-2" points	3	0
Change of "-1" points	16	5
Change of "0" points	51	69
Change of "+1" points	2	1
Change of "+2" points	0	0

50. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Disability Assessment Scale for Domain "Dressing"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Disability Assessment Scale for Domain "Dressing" [units: Participants]		
Change of "-3" points	0	0

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "-2" points	5	2
Change of "-1" points	12	15
Change of "0" points	53	54
Change of "+1" points	3	3
Change of "+2" points	0	0
Missing	0	1

51. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in the Disability Assessment Scale for Domain "Dressing"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 8 in the Disability Assessment Scale for Domain "Dressing" [units: Participants]		

	incobotulinumtoxinA (Xeomin)	Placebo
Change of "-3" points	1	0
Change of "-2" points	3	2
Change of "-1" points	16	13
Change of "0" points	48	56
Change of "+1" points	3	3
Change of "+2" points	0	0
Missing	2	1

52. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Disability Assessment Scale for Domain "Dressing"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75

	incobotulinumtoxinA (Xeomin)	Placebo
Change From Baseline to Week 12 in the Disability Assessment Scale for Domain "Dressing" [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	3	3
Change of "-1" points	16	13
Change of "0" points	47	53
Change of "+1" points	4	4
Change of "+2" points	0	0
Missing	2	2

53. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Disability Assessment Scale for Domain "Dressing"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Disability Assessment Scale for Domain "Dressing" [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	2	2
Change of "-1" points	14	16
Change of "0" points	50	51
Change of "+1" points	5	4
Change of "+2" points	0	0
Missing	2	2

54. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in the Disability Assessment Scale for Domain "Limb Position"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 2 in the Disability Assessment Scale for Domain "Limb Position" [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	2	0
Change of "-1" points	22	8
Change of "0" points	43	65
Change of "+1" points	5	2
Change of "+2" points	0	0

55. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Disability Assessment Scale for Domain "Limb Position"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Disability Assessment Scale for Domain "Limb Position" [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	7	1
Change of "-1" points	25	10
Change of "0" points	37	59
Change of "+1" points	4	4
Change of "+2" points	0	0
Missing	0	1

56. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in the Disability Assessment Scale for Domain "Limb Position"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 8 in the Disability Assessment Scale for Domain "Limb Position" [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	4	1
Change of "-1" points	26	10
Change of "0" points	37	61
Change of "+1" points	4	2
Change of "+2" points	0	0
Missing	2	1

57. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Disability Assessment Scale for Domain "Limb Position"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in the Disability Assessment Scale for Domain "Limb Position" [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	3	3
Change of "-1" points	19	9
Change of "0" points	45	56
Change of "+1" points	3	5
Change of "+2" points	1	0
Missing	2	2

58. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Disability Assessment Scale for Domain "Limb Position"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Disability Assessment Scale for Domain "Limb Position" [units: Participants]		
Change of "-3" points	0	0
Change of "-2" points	1	3
Change of "-1" points	22	14
Change of "0" points	42	51
Change of "+1" points	5	5
Change of "+2" points	1	0
Missing	2	2

59. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 2 in the Disability Assessment Scale for Domain "Pain"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 2
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 2 in the Disability Assessment Scale for Domain "Pain" [units: Participants]		
Change of "-3" points	1	0
Change of "-2" points	3	0
Change of "-1" points	12	5
Change of "0" points	54	69
Change of "+1" points	3	0
Change of "+2" points	0	1

60. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Disability Assessment Scale for Domain "Pain"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Disability Assessment Scale for Domain "Pain" [units: Participants]		
Change of "-3" points	2	0
Change of "-2" points	8	2
Change of "-1" points	11	4
Change of "0" points	46	67
Change of "+1" points	6	1
Change of "+2" points	0	0
Missing	0	1

61. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 8 in the Disability Assessment Scale for Domain "Pain"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 8
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 8 in the Disability Assessment Scale for Domain "Pain" [units: Participants]		
Change of "-3" points	2	0
Change of "-2" points	4	1
Change of "-1" points	11	7
Change of "0" points	49	65
Change of "+1" points	5	0
Change of "+2" points	0	1
Missing	2	1

62. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Disability Assessment Scale for Domain "Pain"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in the Disability Assessment Scale for Domain "Pain" [units: Participants]		
Change of "-3" points	3	0
Change of "-2" points	3	1
Change of "-1" points	10	9
Change of "0" points	52	62
Change of "+1" points	3	0
Change of "+2" points	0	1
Missing	2	2

63. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Disability Assessment Scale for Domain "Pain"
Measure Description	The Disability Assessment Scale consists of the four domains hygiene, dressing, limb position, and pain which were assessed on a 4-point scale with the values 0 (=no disability), 1 (=mild disability), 2 (=moderate disability), and 3 (=severe disability).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Disability Assessment Scale for Domain "Pain" [units: Participants]		
Change of "-3" points	2	0
Change of "-2" points	3	2
Change of "-1" points	11	7
Change of "0" points	51	63
Change of "+1" points	4	0
Change of "+2" points	0	1
Missing	2	2

64. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Cleaning the Palm of the Affected Hand"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection

	Description
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Cleaning the Palm of the Affected Hand" [units: Participants]		
No carer	26	20
No longer necessary	3	0
Less difficult	15	9
Unchanged	24	38
More difficult	5	4
Required for the first time	0	3
Missing	0	1

65. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Cleaning the Palm of the Affected Hand"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Cleaning the Palm of the Affected Hand" [units: Participants]		
No carer	26	22
No longer necessary	2	1
Less difficult	12	4
Unchanged	26	38
More difficult	7	5
Required for the first time	0	3
Missing	0	2

66. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Cleaning the Palm of the Affected Hand"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Cleaning the Palm of the Affected Hand" [units: Participants]		
No carer	27	22
No longer necessary	2	0
Less difficult	8	4
Unchanged	26	36
More difficult	9	5
Required for the first time	1	6
Missing	0	2

67. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Cutting the Fingernails of the Affected Hand"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).

Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Cutting the Fingernails of the Affected Hand" [units: Participants]		
No carer	26	20
No longer necessary	0	0
Less difficult	17	12
Unchanged	19	36
More difficult	11	5
Required for the first time	0	1
Missing	0	1

68. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Cutting the Fingernails of the Affected Hand"

Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Cutting the Fingernails of the Affected Hand" [units: Participants]		
No carer	26	22
No longer necessary	1	0
Less difficult	12	15
Unchanged	21	26
More difficult	13	9
Required for the first time	0	1
Missing	0	2

69. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Cutting the Fingernails of the Affected Hand"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Cutting the Fingernails of the Affected Hand" [units: Participants]		
No carer	27	22
No longer necessary	1	1
Less difficult	12	12
Unchanged	21	26
More difficult	12	10
Required for the first time	0	2

	incobotulinumtoxinA (Xeomin)	Placebo
Missing	0	2

70. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Cleaning the Armpit of the Affected Arm"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Cleaning the Armpit of the Affected Arm" [units: Participants]		
No carer	26	20
No longer necessary	3	0
Less difficult	11	8

	incobotulinumtoxinA (Xeomin)	Placebo
Unchanged	27	38
More difficult	4	6
Required for the first time	2	2
Missing	0	1

71. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Cleaning the Armpit of the Affected Arm"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Cleaning the Armpit of the Affected Arm" [units: Participants]		

	incobotulinumtoxinA (Xeomin)	Placebo
No carer	26	22
No longer necessary	1	2
Less difficult	12	7
Unchanged	25	33
More difficult	6	8
Required for the first time	3	1
Missing	0	2

72. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Cleaning the Armpit of the Affected Arm"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Cleaning the Armpit of the Affected Arm" [units: Participants]		
No carer	27	22
No longer necessary	1	2
Less difficult	12	6
Unchanged	23	32
More difficult	6	9
Required for the first time	4	2
Missing	0	2

73. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Putting the Affected Arm Through the Sleeve (e.g., Coat, Shirt, Jacket)"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection

	Description
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Putting the Affected Arm Through the Sleeve (e.g., Coat, Shirt, Jacket)" [units: Participants]		
No carer	26	20
No longer necessary	2	1
Less difficult	18	11
Unchanged	25	36
More difficult	2	4
Required for the first time	0	2
Missing	0	1

74. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Putting the Affected Arm Through the Sleeve (e.g., Coat, Shirt, Jacket)"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Putting the Affected Arm Through the Sleeve (e.g., Coat, Shirt, Jacket)" [units: Participants]		
No carer	26	22
No longer necessary	2	3
Less difficult	17	13
Unchanged	24	28
More difficult	4	6
Required for the first time	0	1
Missing	0	2

75. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Putting the Affected Arm Through the Sleeve (e.g., Coat, Shirt, Jacket)"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)

Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Putting the Affected Arm Through the Sleeve (e.g., Coat, Shirt, Jacket)" [units: Participants]		
No carer	27	22
No longer necessary	3	4
Less difficult	16	10
Unchanged	24	29
More difficult	3	6
Required for the first time	0	2
Missing	0	2

76. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Applying a Splint on the Affected Arm"

Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 4 in the Carer Burden Scale for Domain "Applying a Splint on the Affected Arm" [units: Participants]		
No carer	26	20
No longer necessary	1	1
Less difficult	5	1
Unchanged	40	51
More difficult	1	0
Required for the first time	0	1
Missing	0	1

77. Secondary Outcome Measure:

Measure Title	Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Applying a Splint on the Affected Arm"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Week 12 in the Carer Burden Scale for Domain "Applying a Splint on the Affected Arm" [units: Participants]		
No carer	26	22
No longer necessary	2	1
Less difficult	2	2
Unchanged	42	46
More difficult	1	0
Required for the first time	0	2

	incobotulinumtoxinA (Xeomin)	Placebo
Missing	0	2

78. Secondary Outcome Measure:

Measure Title	Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Applying a Splint on the Affected Arm"
Measure Description	The Carer Burden Scale evaluates the impact of antispastic medication on the physical burden of the carer. It consists of the following items: A=cleaning the palm of the affected hand; B=cutting the fingernails of the affected hand; C=Cleaning the armpit of the affected arm; D=putting the affected arm through the sleeve; E=applying a splint on the affected arm. Each item was assessed on a 5-point Likert scale which values ranges from 0 (=no difficulty) to 4 (=cannot do the task).
Time Frame	Baseline, Final Visit of the Main Period (to be performed at week 12 after 1st injection at earliest, at week 20 at latest)
Safety Issue?	No

Analysis Population Description

Intention to treat (ITT) as defined as all randomized subjects; missing values were imputed by baseline value, i.e. zero change

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Change From Baseline to Final Visit in the Carer Burden Scale for Domain "Applying a Splint on the Affected Arm" [units: Participants]		
No carer	27	22
No longer necessary	3	1
Less difficult	1	2

	incobotulinumtoxinA (Xeomin)	Placebo
Unchanged	41	45
More difficult	1	1
Required for the first time	0	2
Missing	0	2

79. Other Pre-specified Outcome Measure:

Measure Title	Onset of Treatment Effect [Classified]
Measure Description	Starting with the visit 2 weeks after baseline injection the subject was asked if he/she experienced an treatment effect and if "yes": when. If the subject did not experience an treatment effect he/she was asked again at each of the following visits (at week 4, 8, and 12) of the Main Period until the answer was "yes" or until the final visit of the Main Period was performed. For subjects without any treatment effect the time to onset of effect was censored at the last visit of the Main Period.
Time Frame	Period starting at baseline injection of the Main Period up to onset of treatment effect
Safety Issue?	No

Analysis Population Description

These results are a different presentation of the results of the secondary outcome measure "Time to Onset of Treatment Effect". For subjects without any treatment effect the time to onset of effect was censored at the last visit.

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Measured Values

	incobotulinumtoxinA (Xeomin)	Placebo
Number of Participants Analyzed	73	75
Onset of Treatment Effect [Classified] [units: Participants]		

	incobotulinumtoxinA (Xeomin)	Placebo
Onset at Day 1, 2 or 3	32	14
Onset at Day 4, 5 or 6	12	4
Onset at Day 7, 8 or 9	9	11
Onset at Day 10, 11 or 12	1	6
Onset at Day 13, 14 or 15	3	1
Onset at Day 16, 17 or 18	1	1
Onset at Day 19, 20 or 21	3	3
Onset at Day 22, 23 or 24	0	2
Onset later than Day 25	2	1
Censored	10	32

Reported Adverse Events

Time Frame	All SAEs/AEs during Double-Blind Period After Injection.
Additional Description	The table of "Other Adverse Events" includes all AEs, both non serious and serious. Only results and AEs of the Double-Blind Period are given as the Open-Label Extension Period was a non-controlled study. The investigator asked the patient for AEs systematically at each visit.

Reporting Groups

	Description
incobotulinumtoxinA (Xeomin)	incobotulinumtoxinA (Xeomin) (active ingredient: Clostridium Botulinum neurotoxin Type A free from complexing proteins) powder for solution for injection
Placebo	Placebo to incobotulinumtoxinA (Xeomin) powder for solution for injection Dose (Main Period only): one injection session of solution, prepared by reconstitution of powder with 0.9% NaCl; Mode of administration: intramuscular injection

Serious Adverse Events

	incobotulinumtoxinA (Xeomin)		Placebo	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	4/73 (5.48%)		1/75 (1.33%)	
Ear and labyrinth disorders				
Vertigo [A] †	1/73 (1.37%)	1	0/75 (0%)	0
Infections and infestations				
Cellulitis [A] †	1/73 (1.37%)	1	0/75 (0%)	0
Nervous system disorders				
Epilepsy [A] †	1/73 (1.37%)	1	0/75 (0%)	0
Intracranial haematoma [A] †	0/73 (0%)	0	1/75 (1.33%)	1
Paraparesis [A] †	1/73 (1.37%)	1	0/75 (0%)	0
Status epilepticus [A] †	1/73 (1.37%)	1	0/75 (0%)	0
Respiratory, thoracic and mediastinal disorders				
Bronchitis chronic [A] †	1/73 (1.37%)	1	0/75 (0%)	0
Vascular disorders				
Hypertension [A] †	1/73 (1.37%)	1	0/75 (0%)	0

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (9.1)

Other Adverse Events

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

	incobotulinumtoxinA (Xeomin)		Placebo	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	10/73 (13.7%)		5/75 (6.67%)	
Gastrointestinal disorders				
Diarrhoea [A] †	2/73 (2.74%)	2	2/75 (2.67%)	2
Vomiting [A] †	0/73 (0%)	0	2/75 (2.67%)	2

	incobotulinumtoxinA (Xeomin)		Placebo	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Injury, poisoning and procedural complications				
Contusion [A] †	1/73 (1.37%)	1	2/75 (2.67%)	3
Metabolism and nutrition disorders				
Hypercholesterolaemia [A] †	2/73 (2.74%)	2	1/75 (1.33%)	1
Hyperglycaemia [A] †	3/73 (4.11%)	3	0/75 (0%)	0
Nervous system disorders				
Epilepsy [A] †	2/73 (2.74%)	2	0/75 (0%)	0
Headache [A] †	2/73 (2.74%)	4	1/75 (1.33%)	1

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (9.1)

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.

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:

Name/Official Title: [redacted]
Organization: Merz Pharmaceuticals GmbH
Phone: ++49-69-1503 Ext: [redacted]

Email: [redacted]@merz.de