Clinical trial results:
A Multicenter, Long-term Follow-up Study of the Safety and Efficacy of BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex in Patients with Urinary Incontinence Due to Neurogenic Detrusor Overactivity

Summary

EudraCT number	2009-009216-53
Trial protocol	PT NL GB FR DE IT ES BE AT CZ SK
Global end of trial date	04 September 2013

Results information

Result version number	v1 (current)
This version publication date	01 June 2016
First version publication date	01 June 2016

Trial information

Trial identification

Sponsor protocol code	191622-094

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00876447
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Allergan Limited
Sponsor organisation address	Allergan Limited Marlow International The Parkway, Marlow, United Kingdom, SL7 1YL
Public contact	Allergan Limited EU Regulatory Dept, Allergan Limited, 44 1628 494444, ml-eu_reg_affairs@allergan.com
Scientific contact	Allergan Limited EU Regulatory Dept, Allergan Limited, 44 1628 494444, ml-eu_reg_affairs@allergan.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 March 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 June 2013
Global end of trial reached?	Yes
Global end of trial date	04 September 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term safety and maintenance of efficacy of BOTOX injected into the detrusor for the treatment of urinary incontinence caused by neurogenic detrusor overactivity in patients not been adequately managed with anticholinergic therapy

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 April 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 209
Country: Number of subjects enrolled	United Kingdom: 15
Country: Number of subjects enrolled	Australia: 16
Country: Number of subjects enrolled	Austria: 2
Country: Number of subjects enrolled	Belgium: 16
Country: Number of subjects enrolled	Brazil: 15
Country: Number of subjects enrolled	Canada: 20
Country: Number of subjects enrolled	Czech Republic: 15
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	France: 7
Country: Number of subjects enrolled	Germany: 5
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Netherlands Antilles: 9
Country: Number of subjects enrolled	New Zealand: 1
Country: Number of subjects enrolled	Poland: 9
Country: Number of subjects enrolled	Portugal: 12
Country: Number of subjects enrolled	Taiwan: 3
Country: Number of subjects enrolled	South Africa: 3
Country: Number of subjects enrolled	Singapore: 2
Country: Number of subjects enrolled	Slovakia: 6
Country: Number of subjects enrolled	Russian Federation: 8

Country: Number of subjects enrolled	Ukraine: 12
Worldwide total number of subjects	388
EEA total number of subjects	90

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	363
From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was a long-term follow-up study that enrolled patients after participation in Study 191622-515 or 191622-516. A total of 397 patients were enrolled and 388 patients received at least 1 BOTOX treatment in study 191622-094 or in the preceding studies.

Pre-assignment

Screening details:

The protocol was amended to remove the 300 U dose. Patients ongoing in the study who were treated with 300 U BOTOX prior to the amendment were assigned to 200 U BOTOX for all subsequent treatments. Participant Flow and Baseline Characteristics are based on the first BOTOX dose that patients received.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Carer, Data analyst, Subject, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Botulinum Toxin Type A 300U

Arm description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years.

Arm type	Experimental
Investigational medicinal product name	Botulinum Toxin Type A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years.

Arm title	Botulinum Toxin Type A 200U

Arm description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

Arm type	Experimental
Investigational medicinal product name	Botulinum Toxin Type A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years.

Number of subjects in period 1	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U
Started	185	203
Completed	105	122
Not completed	80	81
Personal reasons	30	28
Adverse event, non-fatal	4	8
Pregnancy	4	2
Other miscellaneous reasons	3	8
Lost to follow-up	6	15
Site closure	19	14
Protocol deviation	9	3
Lack of efficacy	5	3

Baseline characteristics

Reporting groups	
Reporting group title	Botulinum Toxin Type A 300U
Reporting group description:	
Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years.	
Reporting group title	Botulinum Toxin Type A 200U
Reporting group description:	
Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.	

Reporting group values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U	Total
Number of subjects	185	203	388
Age categorical Units: Subjects			
Adults (18-64 years)	171	192	363
From 65-84 years	14	11	25
Age continuous Units: years			
arithmetic mean	46.3	46.5	
standard deviation	± 12.96	± 12.33	-
Gender, Male/Female Units: Participants			
Female	116	118	234
Male	69	85	154

End points

End points reporting groups

Reporting group title	Botulinum Toxin Type A 300U
Reporting group description:	
Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years.	
Reporting group title	Botulinum Toxin Type A 200U
Reporting group description:	
Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.	

Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes

End point title	Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes[1]

End point description:

Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement).

End point type	Primary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 1

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis is reported for this outcome measure

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	183	201		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	4.4 (± 2.54)	4.5 (± 2.64)		
Chg from Study BL at Wk 6 Tmt Cycle1 (N=176, 195)	-3.4 (± 3.16)	-3.2 (± 2.69)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes

End point title	Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes[2]

End point description:

Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement).

End point type	Primary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 2

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis is reported for this outcome measure

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	161	186		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline	4.5 (± 2.62)	4.6 (± 2.71)		
Chg from Study BL at Wk 6 Tmt Cycle2 (N=153, 175)	-3.5 (± 3.13)	-3.3 (± 2.85)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes

End point title	Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes[3]

End point description:

Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement).

End point type	Primary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 3

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis is reported for this outcome measure

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	173		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline	4.4 (± 2.33)	4.6 (± 2.65)		
Chg from Study BL at Wk 6 Tmt Cycle3 (N=109, 164)	-3.3 (± 2.39)	-3.5 (± 2.96)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes

End point title	Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes[4]

End point description:

Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement).

End point type	Primary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 4

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis is reported for this outcome measure

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	149		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline	4.4 (± 2.13)	4.4 (± 2.57)		
Chg from Study BL at Wk 6 Tmt Cycle4 (N=62, 141)	-3.4 (± 2.57)	-3.5 (± 2.61)		

Statistical analyses

No statistical analyses for this end point

Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes

End point title	Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes[5]

End point description:

Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement).

End point type	Primary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 5

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No Statistical Analysis is reported for this outcome measure

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	108		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline	4.1 (± 2.34)	4.6 (± 2.57)		
Chg from Study BL at Wk 6 Tmt Cycle5 (N=29, 99)	-3.7 (± 2.82)	-3.6 (± 2.27)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

End point title	Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

End point description:

The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 1

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	185	202		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline	33.9 (± 18.19)	34.4 (± 18.18)		
Chg from Study BL at Wk 6 Tmt Cycle1 (N=180, 199)	32.3 (± 26.07)	30.3 (± 26.37)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

End point title	Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

End point description:

The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 2

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	162	185		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline	33.3 (± 18.17)	33.8 (± 18.17)		
Chg from Study BL at Wk 6 Tmt Cycle2 (N=157, 178)	31.4 (± 27.73)	33.5 (± 26.23)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Incontinence Quality of Life

Instrument (I-QOL) Total Summary Score

End point title	Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

End point description:

The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 3

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	118	173		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline	32.5 (± 17.83)	34.8 (± 18.95)		
Chg from Study BL at Wk 6 Tmt Cycle3 (N=114, 164)	28.8 (± 28.96)	30.4 (± 29.25)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

End point title	Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

End point description:

The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 4

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	66	151		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline	27.9 (± 16.66)	35.5 (± 17.7)		
Chg from Study BL at Wk 6 Tmt Cycle4 (N=63, 147)	30.4 (± 31.77)	30.1 (± 26.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

End point title	Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

End point description:

The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 5

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	109		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline	32 (± 16.13)	33 (± 19.61)		
Chg from Study BL at Wk 6 Tmt Cycle5 (N=28, 100)	36.6 (± 28.28)	27.1 (± 24.54)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in Volume Per Void

End point title	Change from Study Baseline in Volume Per Void

End point description:

The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 1

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	196		
Units: Milliliters (mL)				
arithmetic mean (standard deviation)				
Study Baseline	147.3 (± 90.15)	154.2 (± 96.54)		
Chg from Study BL at Wk 6 Tmt Cycle1 (N=168, 186)	133.8 (± 137.23)	133.2 (± 128.19)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in Volume Per Void

End point title	Change from Study Baseline in Volume Per Void

End point description:

The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 2

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	157	181		
Units: Milliliters (mL)				
arithmetic mean (standard deviation)				

Study Baseline	149.8 (± 91.03)	151.9 (± 95.22)		
Chg from Study BL at Wk 6 Tmt Cycle2 (N=146, 168)	148 (± 134.45)	135.1 (± 127.62)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in Volume Per Void

End point title	Change from Study Baseline in Volume Per Void

End point description:

The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 3

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114	168		
Units: Milliliters (mL)				
arithmetic mean (standard deviation)				
Study Baseline	155 (± 90.7)	149.6 (± 91.12)		
Chg from Study BL at Wk 6 Tmt Cycle3 (N=105, 158)	166.9 (± 133.59)	157.5 (± 129.81)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in Volume Per Void

End point title	Change from Study Baseline in Volume Per Void

End point description:

The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 4

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65	143		
Units: Milliliters (mL)				
arithmetic mean (standard deviation)				
Study Baseline	159.7 (± 89.37)	151.7 (± 93.65)		
Chg from Study BL at Wk 6 Tmt Cycle4 (N=61, 135)	170.8 (± 128.26)	147.3 (± 122.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in Volume Per Void

End point title	Change from Study Baseline in Volume Per Void

End point description:

The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement.

End point type	Secondary

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 5

End point values	Botulinum Toxin Type A 300U	Botulinum Toxin Type A 200U		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	104		
Units: Milliliters (mL)				
arithmetic mean (standard deviation)				
Study Baseline	182.7 (± 85.03)	140.8 (± 91.32)		
Chg from Study BL at Wk 6 Tmt Cycle5 (N=28, 95)	163.5 (± 106.44)	160.2 (± 119.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were recorded from signing the informed consent to the end of study (Week 156).

Adverse event reporting additional description:

The Botox-Treated Population includes all patients who received at least 1 BOTOX treatment (in Study 191622-094, 191622-515 or 191622-516) and is used to assess adverse events (AEs) and serious adverse events (SAEs). AEs and SAEs are reported by treatment cycle.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	Botulinum Toxin Type A 300U Treatment Cycle 1

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 1

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

Reporting group title	Botulinum Toxin Type A 300U Treatment Cycle 2

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 2

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

Reporting group title	Botulinum Toxin Type A 300U Treatment Cycle 3

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 3

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

Reporting group title	Botulinum Toxin Type A 300U Treatment Cycle 4

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 4

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

Reporting group title	Botulinum Toxin Type A 300U Treatment Cycle 5

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 5

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

Reporting group title	Botulinum Toxin Type A 300U Treatment Cycle 6

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 6

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

Reporting group title	Botulinum Toxin Type A 300U Treatment Cycle 7

Reporting group description:	
Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.	
Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 7
Reporting group description:	
Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.	
Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 8
Reporting group description:	
Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.	
Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 9
Reporting group description:	
Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.	
Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 10
Reporting group description:	
Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.	
Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 11
Reporting group description:	
Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.	
Reporting group title	Botulinum Toxin Type A 200U Treatment Cycle 12
Reporting group description:	
Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.	

Serious adverse events	Botulinum Toxin Type A 300U Treatment Cycle 1	Botulinum Toxin Type A 200U Treatment Cycle 1	Botulinum Toxin Type A 300U Treatment Cycle 2
Total subjects affected by serious adverse events			
subjects affected / exposed	28 / 185 (15.14%)	35 / 203 (17.24%)	26 / 163 (15.95%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer	Additional description: Males Only		
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 185 (0.00%)	2 / 203 (0.99%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Squamous Cell Carcinoma			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Neoplasm			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma	Additional description: Females Only		
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Ischaemia			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion Induced	Additional description: Females Only		
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse Drug Reaction			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	2 / 203 (0.99%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Dislocation			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Deployment Issue			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Healing			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Malfunction			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Epididymitis	Additional description: Males Only		
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Prolapse			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erectile Dysfunction	Additional description: Males Only		

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental Status Changes			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Psychosis			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Urine Cytology Abnormal			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical observation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Craniocerebral Injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional Hernia			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal Haematoma	Additional description: Males Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Fracture			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Multiple Sclerosis Relapse			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 185 (2.16%)	4 / 203 (1.97%)	4 / 163 (2.45%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia Gravis			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Sclerosis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	2 / 163 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Compression			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision Blurred			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal Obstruction			

subjects affected / exposed	2 / 185 (1.08%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ischaemic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haemorrhoidal Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			

subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Decubitus Ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 185 (1.08%)	4 / 203 (1.97%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Haemorrhage			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Neck Obstruction			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Stenosis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic Bladder			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydroureter			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Lumbar Spinal Stenosis			
subjects affected / exposed	2 / 185 (1.08%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	1 / 185 (0.54%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	2 / 203 (0.99%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral Foraminal Stenosis			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Pain			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus-Like Syndrome			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility Decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 185 (3.78%)	5 / 203 (2.46%)	3 / 163 (1.84%)
occurrences causally related to treatment / all	2 / 7	3 / 5	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 185 (0.54%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			

subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 185 (0.54%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Sepsis			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	1 / 163 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of Salivary Gland			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Botulinum Toxin Type A 200U Treatment Cycle 2	Botulinum Toxin Type A 300U Treatment Cycle 3	Botulinum Toxin Type A 200U Treatment Cycle 3
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 187 (11.23%)	20 / 119 (16.81%)	19 / 175 (10.86%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer	Additional description: Males Only		

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Neoplasm			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma	Additional description: Females Only		
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	2 / 175 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Ischaemia			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion Induced	Additional description: Females Only		
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse Drug Reaction			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Dislocation			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Deployment Issue			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Healing			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Malfunction			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Epididymitis	Additional description: Males Only		

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Prolapse			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erectile Dysfunction	Additional description: Males Only		
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental Status Changes			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Psychosis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Urine Cytology Abnormal			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical observation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
Craniocerebral Injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional Hernia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal Haematoma	Additional description: Males Only		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Fracture			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Multiple Sclerosis Relapse			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	3 / 119 (2.52%)	3 / 175 (1.71%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia Gravis			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Sclerosis			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Compression			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision Blurred			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal Obstruction			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ischaemic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Decubitus Ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	2 / 175 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Haemorrhage			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Neck Obstruction			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Stenosis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic Bladder			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hydronephrosis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydroureter			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral Foraminal Stenosis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus-Like Syndrome			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 187 (0.53%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility Decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	3 / 119 (2.52%)	2 / 175 (1.14%)
occurrences causally related to treatment / all	0 / 1	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	3 / 187 (1.60%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Escherichia Sepsis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 187 (0.00%)	2 / 119 (1.68%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 187 (0.53%)	2 / 119 (1.68%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Localised Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of Salivary Gland			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Botulinum Toxin Type A 300U Treatment Cycle 4	Botulinum Toxin Type A 200U Treatment Cycle 4	Botulinum Toxin Type A 300U Treatment Cycle 5
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 69 (15.94%)	20 / 153 (13.07%)	5 / 34 (14.71%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	2 / 34 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer	Additional description: Males Only		
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Neoplasm			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Ductal Breast Carcinoma			

subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma	Additional description: Females Only		
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Ischaemia			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion Induced	Additional description: Females Only		
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Adverse Drug Reaction			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Dislocation			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Deployment Issue			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Healing			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Malfunction			

subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Epididymitis	Additional description: Males Only		
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Prolapse			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erectile Dysfunction	Additional description: Males Only		
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental Status Changes			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Psychosis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Urine Cytology Abnormal			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical observation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Craniocerebral Injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Incisional Hernia			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Scar			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal Haematoma	Additional description: Males Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Fracture			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Multiple Sclerosis Relapse			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 69 (5.80%)	2 / 153 (1.31%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia Gravis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Sclerosis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Compression			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision Blurred			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal Obstruction			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ischaemic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Decubitus Ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Haemorrhage			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Neck Obstruction			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Stenosis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic Bladder			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			

alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydroureter			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral Foraminal Stenosis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus-Like Syndrome			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility Decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Sepsis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			

subjects affected / exposed	0 / 69 (0.00%)	3 / 153 (1.96%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of Salivary Gland			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			

subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Botulinum Toxin Type A 200U Treatment Cycle 5	Botulinum Toxin Type A 300U Treatment Cycle 6	Botulinum Toxin Type A 200U Treatment Cycle 6
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 110 (10.00%)	0 / 16 (0.00%)	9 / 70 (12.86%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer	Additional description: Males Only		
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Neoplasm			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma	Additional description: Females Only		
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Ischaemia			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion Induced	Additional description: Females Only		
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse Drug Reaction			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Dislocation			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Deployment Issue			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Healing			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Malfunction			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Epididymitis	Additional description: Males Only		
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Prolapse			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erectile Dysfunction	Additional description: Males Only		
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental Status Changes			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Psychosis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Urine Cytology Abnormal			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical observation			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Craniocerebral Injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional Hernia			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Joint Dislocation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal Haematoma	Additional description: Males Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Fracture			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Myocardial Infarction			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Multiple Sclerosis Relapse			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	3 / 70 (4.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Spasticity			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia Gravis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Sclerosis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Compression			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision Blurred			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal Obstruction			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ischaemic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Decubitus Ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Haemorrhage			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Neck Obstruction			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Stenosis			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic Bladder			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydroureter			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Lumbar Spinal Stenosis			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral Foraminal Stenosis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus-Like Syndrome			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility Decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Sepsis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of Salivary Gland			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Botulinum Toxin Type A 300U Treatment Cycle 7	Botulinum Toxin Type A 200U Treatment Cycle 7	Botulinum Toxin Type A 200U Treatment Cycle 8
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	6 / 48 (12.50%)	0 / 36 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer	Additional description: Males Only		

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Neoplasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma	Additional description: Females Only		
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Ischaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion Induced	Additional description: Females Only		
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse Drug Reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Dislocation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Deployment Issue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Healing			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Malfunction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Epididymitis	Additional description: Males Only		

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Prolapse			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erectile Dysfunction	Additional description: Males Only		
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental Status Changes			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Psychosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Urine Cytology Abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical observation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
Craniocerebral Injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional Hernia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal Haematoma	Additional description: Males Only		
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Fracture			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Multiple Sclerosis Relapse			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	2 / 48 (4.17%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia Gravis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Sclerosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Compression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision Blurred			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal Obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ischaemic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Decubitus Ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Haemorrhage			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Neck Obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic Bladder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hydronephrosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydroureter			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral Foraminal Stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus-Like Syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility Decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Escherichia Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Localised Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of Salivary Gland			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Botulinum Toxin Type A 200U Treatment Cycle 9	Botulinum Toxin Type A 200U Treatment Cycle 10	Botulinum Toxin Type A 200U Treatment Cycle 11
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 22 (9.09%)	1 / 11 (9.09%)	0 / 5 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer	Additional description: Males Only		
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Neoplasm			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Ductal Breast Carcinoma			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma	Additional description: Females Only		
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Ischaemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion Induced	Additional description: Females Only		
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Adverse Drug Reaction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Cardiac Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Dislocation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Deployment Issue			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Healing			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Malfunction			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Epididymitis	Additional description: Males Only		
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Prolapse			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erectile Dysfunction	Additional description: Males Only		
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental Status Changes			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Psychosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Urine Cytology Abnormal			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical observation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Craniocerebral Injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Incisional Hernia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Scar			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal Haematoma	Additional description: Males Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	1 / 22 (4.55%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial Infarction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Multiple Sclerosis Relapse			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia Gravis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Sclerosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Compression			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision Blurred			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal Obstruction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ischaemic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Decubitus Ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Neck Obstruction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Stenosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic Bladder			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydroureter			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral Foraminal Stenosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus-Like Syndrome			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility Decreased			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urinary Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Sepsis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of Salivary Gland			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	1 / 22 (4.55%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Botulinum Toxin Type A 200U Treatment Cycle 12		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer	Additional description: Males Only		
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast Cancer			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid Neoplasm			

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous Cell Carcinoma of Skin				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Invasive Ductal Breast Carcinoma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glioblastoma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine Leiomyoma	Additional description: Females Only			
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Hypertension				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral Ischaemia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deep Vein Thrombosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral Vascular Disorder				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
Abortion Induced	Additional description: Females Only			
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Adverse Drug Reaction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-Cardiac Chest Pain				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device Dislocation				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema Peripheral				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device Deployment Issue				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impaired Healing				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device Malfunction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Anaphylactic Reaction				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Epididymitis	Additional description: Males Only			
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic Prolapse				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erectile Dysfunction	Additional description: Males Only			
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Asthma				

alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory Failure				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia Aspiration				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary Embolism				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Mental Status Changes				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute Psychosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Confusional State				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Urine Cytology Abnormal				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medical observation				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Craniocerebral Injury				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon Rupture				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Fall				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Forearm Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incisional Hernia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower Limb Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Overdose				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hip Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Joint Dislocation				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Compression Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scar				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scrotal Haematoma	Additional description: Males Only			
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post Procedural Haemorrhage				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foot Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankle Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				

Myocardial Infarction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute myocardial infarction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular Block				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina Pectoris				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial Fibrillation				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Multiple Sclerosis Relapse				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle Spasticity				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular Accident			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic Stroke			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myasthenia Gravis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple Sclerosis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraparesis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical myelopathy			

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Cord Compression				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Neutropenia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Vision Blurred				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Intestinal Obstruction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical Hernia				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocutaneous Fistula				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Faecaloma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis Ischaemic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal Haemorrhage				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large Intestine Perforation				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower Gastrointestinal Haemorrhage				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small Intestinal Obstruction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Volvulus				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis Acute				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Decubitus Ulcer				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Urinary Retention				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urethral Haemorrhage				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress Urinary Incontinence				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder Neck Obstruction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urethral Stenosis				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neurogenic Bladder				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Incontinence				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydronephrosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydroureter				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Hyperthyroidism				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Lumbar Spinal Stenosis				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spondylolisthesis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foot Deformity				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral Disc Protrusion				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular Weakness				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back Pain				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vertebral Foraminal Stenosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone Pain				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lupus-Like Syndrome				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Costochondritis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exostosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthralgia				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical Spinal Stenosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rotator Cuff Syndrome				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mobility Decreased				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Urinary Tract Infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium Difficile Colitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper Respiratory Tract Infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Infection Bacterial				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound Infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia Sepsis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Necrotising Fasciitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paronychia				

alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis Acute				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic Candida				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised Infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess of Salivary Gland				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin Infection				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device Related Infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parotitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral Infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post Procedural Infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subcutaneous Abscess				

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Obesity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Botulinum Toxin Type A 300U Treatment Cycle 1	Botulinum Toxin Type A 200U Treatment Cycle 1	Botulinum Toxin Type A 300U Treatment Cycle 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	154 / 185 (83.24%)	170 / 203 (83.74%)	126 / 163 (77.30%)
General disorders and administration site conditions			
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 185 (3.24%)	8 / 203 (3.94%)	3 / 163 (1.84%)
occurrences (all)	6	10	5

Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 185 (3.24%)	13 / 203 (6.40%)	4 / 163 (2.45%)
occurrences (all)	8	14	4
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 185 (2.16%)	17 / 203 (8.37%)	5 / 163 (3.07%)
occurrences (all)	4	19	6
Reproductive system and breast disorders			
Ovarian Cyst	Additional description: Females Only		
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pruritus	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences (all)	0	3	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis Seasonal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 185 (2.70%)	6 / 203 (2.96%)	3 / 163 (1.84%)
occurrences (all)	6	6	4
Investigations			
Expanded Disability Status Scale Score Increased			
subjects affected / exposed	7 / 185 (3.78%)	10 / 203 (4.93%)	13 / 163 (7.98%)
occurrences (all)	9	10	14
Haemoglobin Decreased			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Central Nervous System Function Test Abnormal			

subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 185 (2.70%)	6 / 203 (2.96%)	7 / 163 (4.29%)
occurrences (all)	6	13	9
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	3 / 203 (1.48%)	1 / 163 (0.61%)
occurrences (all)	0	3	1
Hand Fracture			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 185 (0.00%)	2 / 203 (0.99%)	2 / 163 (1.23%)
occurrences (all)	0	5	3
Thermal Burn			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	2 / 203 (0.99%)	0 / 163 (0.00%)
occurrences (all)	0	2	0
Cardiac disorders			
Bundle Branch Block Right			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 185 (2.16%)	1 / 203 (0.49%)	2 / 163 (1.23%)
occurrences (all)	5	1	2
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 185 (4.32%)	9 / 203 (4.43%)	3 / 163 (1.84%)
occurrences (all)	8	9	3
Blood and lymphatic system disorders			

Leukocytosis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 185 (3.78%)	10 / 203 (4.93%)	7 / 163 (4.29%)
occurrences (all)	7	13	9
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 185 (1.08%)	1 / 203 (0.49%)	5 / 163 (3.07%)
occurrences (all)	2	1	5
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 185 (2.16%)	8 / 203 (3.94%)	7 / 163 (4.29%)
occurrences (all)	5	12	7
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 185 (2.70%)	10 / 203 (4.93%)	3 / 163 (1.84%)
occurrences (all)	5	11	4
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 185 (1.62%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	4	0	0
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	42 / 185 (22.70%)	41 / 203 (20.20%)	13 / 163 (7.98%)
occurrences (all)	50	44	13
Pollakiuria			

subjects affected / exposed	4 / 185 (2.16%)	5 / 203 (2.46%)	2 / 163 (1.23%)
occurrences (all)	4	5	2
Urine abnormality			
subjects affected / exposed	1 / 185 (0.54%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences (all)	2	1	0
Endocrine disorders			
Hypothyroidism			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 185 (0.54%)	2 / 203 (0.99%)	1 / 163 (0.61%)
occurrences (all)	1	2	1
Musculoskeletal and connective tissue disorders			
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 185 (2.70%)	8 / 203 (3.94%)	10 / 163 (6.13%)
occurrences (all)	6	10	10
Fracture Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	100 / 185 (54.05%)	118 / 203 (58.13%)	86 / 163 (52.76%)
occurrences (all)	226	263	177
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	10 / 185 (5.41%)	9 / 203 (4.43%)	7 / 163 (4.29%)
occurrences (all)	12	12	7
Vulvovaginal Mycotic Infection	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 185 (2.16%)	7 / 203 (3.45%)	4 / 163 (2.45%)
occurrences (all)	4	7	4
Upper Respiratory Tract Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 185 (3.78%)	6 / 203 (2.96%)	3 / 163 (1.84%)
occurrences (all)	10	7	3
Herpes Zoster			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 185 (0.54%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences (all)	1	1	0
Fungal Skin Infection			
subjects affected / exposed	1 / 185 (0.54%)	2 / 203 (0.99%)	0 / 163 (0.00%)
occurrences (all)	1	2	0
Gastroenteritis Norovirus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis Acute			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
Staphylococcal Infection			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 185 (0.00%)	2 / 203 (0.99%)	0 / 163 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Botulinum Toxin Type A 200U Treatment Cycle 2	Botulinum Toxin Type A 300U Treatment Cycle 3	Botulinum Toxin Type A 200U Treatment Cycle 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	147 / 187 (78.61%)	89 / 119 (74.79%)	123 / 175 (70.29%)
General disorders and administration site conditions			
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 187 (1.60%)	4 / 119 (3.36%)	6 / 175 (3.43%)
occurrences (all)	3	4	6
Fatigue			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	6 / 187 (3.21%)	3 / 119 (2.52%)	4 / 175 (2.29%)
occurrences (all)	7	3	5
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 187 (2.14%)	2 / 119 (1.68%)	4 / 175 (2.29%)
occurrences (all)	7	2	5
Reproductive system and breast disorders			
Ovarian Cyst	Additional description: Females Only		
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pruritus	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis Seasonal			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 187 (2.67%)	3 / 119 (2.52%)	0 / 175 (0.00%)
occurrences (all)	5	4	0
Investigations			
Expanded Disability Status Scale Score Increased			
subjects affected / exposed	12 / 187 (6.42%)	4 / 119 (3.36%)	8 / 175 (4.57%)
occurrences (all)	18	4	9
Haemoglobin Decreased			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Central Nervous System Function Test Abnormal			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 187 (3.21%)	1 / 119 (0.84%)	9 / 175 (5.14%)
occurrences (all)	7	2	9
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	2 / 119 (1.68%)	1 / 175 (0.57%)
occurrences (all)	0	2	1
Hand Fracture			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences (all)	1	0	1
Thermal Burn			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	2 / 119 (1.68%)	1 / 175 (0.57%)
occurrences (all)	0	2	1
Cardiac disorders			
Bundle Branch Block Right			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 187 (1.60%)	1 / 119 (0.84%)	0 / 175 (0.00%)
occurrences (all)	3	1	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 187 (2.14%)	3 / 119 (2.52%)	4 / 175 (2.29%)
occurrences (all)	4	3	4
Blood and lymphatic system disorders			

Leukocytosis			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 187 (3.21%)	3 / 119 (2.52%)	1 / 175 (0.57%)
occurrences (all)	6	3	1
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 187 (1.07%)	1 / 119 (0.84%)	4 / 175 (2.29%)
occurrences (all)	2	1	5
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 187 (1.07%)	3 / 119 (2.52%)	1 / 175 (0.57%)
occurrences (all)	2	3	1
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 187 (2.67%)	5 / 119 (4.20%)	4 / 175 (2.29%)
occurrences (all)	6	5	4
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 187 (1.07%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences (all)	2	0	1
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	15 / 187 (8.02%)	8 / 119 (6.72%)	11 / 175 (6.29%)
occurrences (all)	15	9	11
Pollakiuria			

subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	2 / 175 (1.14%)
occurrences (all)	0	0	2
Urine abnormality			
subjects affected / exposed	1 / 187 (0.53%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	1 / 119 (0.84%)	1 / 175 (0.57%)
occurrences (all)	1	1	1
Musculoskeletal and connective tissue disorders			
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 187 (4.28%)	2 / 119 (1.68%)	6 / 175 (3.43%)
occurrences (all)	10	2	8
Fracture Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	92 / 187 (49.20%)	61 / 119 (51.26%)	84 / 175 (48.00%)
occurrences (all)	161	111	144
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 187 (2.67%)	6 / 119 (5.04%)	1 / 175 (0.57%)
occurrences (all)	5	6	1
Vulvovaginal Mycotic Infection	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 187 (2.67%)	2 / 119 (1.68%)	3 / 175 (1.71%)
occurrences (all)	6	2	4
Upper Respiratory Tract Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 187 (1.07%)	0 / 119 (0.00%)	10 / 175 (5.71%)
occurrences (all)	2	0	10
Herpes Zoster			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 187 (0.53%)	3 / 119 (2.52%)	1 / 175 (0.57%)
occurrences (all)	1	3	1
Fungal Skin Infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
Gastroenteritis Norovirus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis Acute			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Staphylococcal Infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Botulinum Toxin Type A 300U Treatment Cycle 4	Botulinum Toxin Type A 200U Treatment Cycle 4	Botulinum Toxin Type A 300U Treatment Cycle 5
Total subjects affected by non-serious adverse events			
subjects affected / exposed	51 / 69 (73.91%)	109 / 153 (71.24%)	19 / 34 (55.88%)
General disorders and administration site conditions			
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 69 (4.35%)	2 / 153 (1.31%)	2 / 34 (5.88%)
occurrences (all)	3	3	2
Fatigue			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	3 / 153 (1.96%)	0 / 34 (0.00%)
occurrences (all)	0	3	0
Reproductive system and breast disorders			
Ovarian Cyst	Additional description: Females Only		
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Vulvovaginal Pruritus	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis Seasonal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	1 / 153 (0.65%)	3 / 34 (8.82%)
occurrences (all)	1	1	3
Investigations			
Expanded Disability Status Scale Score Increased			
subjects affected / exposed	2 / 69 (2.90%)	5 / 153 (3.27%)	0 / 34 (0.00%)
occurrences (all)	2	7	0
Haemoglobin Decreased			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Central Nervous System Function Test Abnormal			

subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 69 (2.90%)	5 / 153 (3.27%)	0 / 34 (0.00%)
occurrences (all)	2	7	0
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences (all)	1	1	0
Hand Fracture			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 69 (0.00%)	2 / 153 (1.31%)	0 / 34 (0.00%)
occurrences (all)	0	2	0
Thermal Burn			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	1 / 153 (0.65%)	1 / 34 (2.94%)
occurrences (all)	0	1	1
Cardiac disorders			
Bundle Branch Block Right			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	1 / 153 (0.65%)	2 / 34 (5.88%)
occurrences (all)	1	1	3
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	1 / 153 (0.65%)	1 / 34 (2.94%)
occurrences (all)	1	1	1
Blood and lymphatic system disorders			

Leukocytosis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 69 (4.35%)	4 / 153 (2.61%)	2 / 34 (5.88%)
occurrences (all)	3	5	2
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	2 / 153 (1.31%)	1 / 34 (2.94%)
occurrences (all)	1	2	1
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences (all)	2	1	0
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	7 / 153 (4.58%)	0 / 34 (0.00%)
occurrences (all)	1	8	0
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	4 / 153 (2.61%)	0 / 34 (0.00%)
occurrences (all)	0	4	0
Pollakiuria			

subjects affected / exposed	0 / 69 (0.00%)	3 / 153 (1.96%)	1 / 34 (2.94%)
occurrences (all)	0	3	1
Urine abnormality			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 69 (2.90%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	3	0	0
Fracture Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	28 / 69 (40.58%)	60 / 153 (39.22%)	11 / 34 (32.35%)
occurrences (all)	46	89	16
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	3 / 153 (1.96%)	0 / 34 (0.00%)
occurrences (all)	1	4	0
Vulvovaginal Mycotic Infection	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	1 / 153 (0.65%)	0 / 34 (0.00%)
occurrences (all)	1	2	0
Upper Respiratory Tract Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	2 / 153 (1.31%)	0 / 34 (0.00%)
occurrences (all)	1	2	0
Herpes Zoster			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 69 (1.45%)	2 / 153 (1.31%)	0 / 34 (0.00%)
occurrences (all)	1	2	0
Fungal Skin Infection			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Norovirus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis Acute			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Staphylococcal Infection			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	1 / 34 (2.94%)
occurrences (all)	0	0	1

Non-serious adverse events	Botulinum Toxin Type A 200U Treatment Cycle 5	Botulinum Toxin Type A 300U Treatment Cycle 6	Botulinum Toxin Type A 200U Treatment Cycle 6
Total subjects affected by non-serious adverse events			
subjects affected / exposed	72 / 110 (65.45%)	8 / 16 (50.00%)	46 / 70 (65.71%)
General disorders and administration site conditions			
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	2 / 70 (2.86%)
occurrences (all)	1	0	2
Fatigue			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	2 / 110 (1.82%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences (all)	2	0	1
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Ovarian Cyst	Additional description: Females Only		
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pruritus	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis Seasonal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
Investigations			
Expanded Disability Status Scale Score Increased			
subjects affected / exposed	3 / 110 (2.73%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences (all)	3	0	1
Haemoglobin Decreased			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Central Nervous System Function Test Abnormal			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 110 (3.64%)	0 / 16 (0.00%)	3 / 70 (4.29%)
occurrences (all)	4	0	3
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	1 / 16 (6.25%)	1 / 70 (1.43%)
occurrences (all)	0	1	1
Hand Fracture			
subjects affected / exposed	0 / 110 (0.00%)	1 / 16 (6.25%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bundle Branch Block Right			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	1 / 16 (6.25%)	1 / 70 (1.43%)
occurrences (all)	0	1	1
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 110 (2.73%)	0 / 16 (0.00%)	2 / 70 (2.86%)
occurrences (all)	3	0	2
Blood and lymphatic system disorders			

Leukocytosis			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 110 (3.64%)	0 / 16 (0.00%)	4 / 70 (5.71%)
occurrences (all)	4	0	5
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 110 (2.73%)	1 / 16 (6.25%)	2 / 70 (2.86%)
occurrences (all)	4	1	2
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 110 (2.73%)	1 / 16 (6.25%)	1 / 70 (1.43%)
occurrences (all)	3	1	1
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 110 (3.64%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences (all)	5	0	1
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences (all)	1	0	1
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 110 (1.82%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	3	0	0
Pollakiuria			

subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Urine abnormality			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 110 (0.91%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 110 (1.82%)	0 / 16 (0.00%)	2 / 70 (2.86%)
occurrences (all)	2	0	2
Fracture Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	1 / 16 (6.25%)	0 / 70 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	1 / 110 (0.91%)	1 / 16 (6.25%)	0 / 70 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	35 / 110 (31.82%)	4 / 16 (25.00%)	21 / 70 (30.00%)
occurrences (all)	58	5	32
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 110 (1.82%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	2	0	0
Vulvovaginal Mycotic Infection	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	1 / 70 (1.43%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 110 (1.82%)	1 / 16 (6.25%)	0 / 70 (0.00%)
occurrences (all)	2	1	1
Herpes Zoster			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 110 (1.82%)	0 / 16 (0.00%)	2 / 70 (2.86%)
occurrences (all)	2	0	2
Fungal Skin Infection			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Norovirus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis Acute			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Staphylococcal Infection			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Botulinum Toxin Type A 300U Treatment Cycle 7	Botulinum Toxin Type A 200U Treatment Cycle 7	Botulinum Toxin Type A 200U Treatment Cycle 8
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 8 (37.50%)	28 / 48 (58.33%)	23 / 36 (63.89%)
General disorders and administration site conditions			
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	2 / 48 (4.17%)	2 / 36 (5.56%)
occurrences (all)	0	2	2
Fatigue			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	2 / 48 (4.17%)	1 / 36 (2.78%)
occurrences (all)	0	2	2
Reproductive system and breast disorders			
Ovarian Cyst	Additional description: Females Only		
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pruritus	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Rhinitis Seasonal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Investigations			
Expanded Disability Status Scale Score Increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	2 / 36 (5.56%)
occurrences (all)	0	2	2
Haemoglobin Decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Central Nervous System Function Test Abnormal			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	3 / 48 (6.25%)	3 / 36 (8.33%)
occurrences (all)	0	7	6
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hand Fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	3 / 48 (6.25%)	0 / 36 (0.00%)
occurrences (all)	0	3	0
Thermal Burn			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bundle Branch Block Right			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	2 / 36 (5.56%)
occurrences (all)	0	1	2
Blood and lymphatic system disorders			

Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	3 / 48 (6.25%)	0 / 36 (0.00%)
occurrences (all)	0	4	0
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	2
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	1 / 36 (2.78%)
occurrences (all)	0	1	2
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	3 / 48 (6.25%)	1 / 36 (2.78%)
occurrences (all)	0	3	1
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			

subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Urine abnormality			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 8 (12.50%)	1 / 48 (2.08%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Fracture Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	3 / 8 (37.50%)	15 / 48 (31.25%)	12 / 36 (33.33%)
occurrences (all)	6	19	20
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 48 (2.08%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Vulvovaginal Mycotic Infection	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 8 (12.50%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Fungal Skin Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Norovirus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis Acute			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Staphylococcal Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Botulinum Toxin Type A 200U Treatment Cycle 9	Botulinum Toxin Type A 200U Treatment Cycle 10	Botulinum Toxin Type A 200U Treatment Cycle 11
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 22 (59.09%)	5 / 11 (45.45%)	3 / 5 (60.00%)
General disorders and administration site conditions			
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 22 (4.55%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Fatigue			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 22 (4.55%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Reproductive system and breast disorders			
Ovarian Cyst	Additional description: Females Only		
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pruritus	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis Seasonal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 22 (4.55%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Investigations			
Expanded Disability Status Scale Score Increased			
subjects affected / exposed	1 / 22 (4.55%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Haemoglobin Decreased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Central Nervous System Function Test Abnormal			

subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 22 (4.55%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hand Fracture			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 22 (4.55%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Thermal Burn			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Cardiac disorders			
Bundle Branch Block Right			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Leukocytosis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			

subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Urine abnormality			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fracture Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	7 / 22 (31.82%)	1 / 11 (9.09%)	1 / 5 (20.00%)
occurrences (all)	11	2	1
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Mycotic Infection	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes Zoster			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fungal Skin Infection			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis Norovirus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Osteomyelitis Acute			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Staphylococcal Infection			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 11 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Botulinum Toxin Type A 200U Treatment Cycle 12		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)		
General disorders and administration site conditions			
Oedema Peripheral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Fatigue			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Ovarian Cyst	Additional description: Females Only		
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Vulvovaginal Pruritus	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Rhinitis Seasonal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Depression			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Investigations			
Expanded Disability Status Scale Score Increased			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Haemoglobin Decreased			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Central Nervous System Function Test Abnormal			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Hand Fracture			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Thermal Burn			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Bundle Branch Block Right			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Muscle Spasticity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Headache			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			

Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2 (50.00%)		
occurrences (all)	1		
Renal and urinary disorders			
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pollakiuria			

subjects affected / exposed	1 / 2 (50.00%)		
occurrences (all)	1		
Urine abnormality			
subjects affected / exposed	1 / 2 (50.00%)		
occurrences (all)	1		
Endocrine disorders			
Hypothyroidism			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Muscular Weakness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Fracture Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Tendonitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	1 / 2 (50.00%)		
occurrences (all)	1		
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Vulvovaginal Mycotic Infection	Additional description: Females Only		
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Upper Respiratory Tract Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Herpes Zoster			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Fungal Skin Infection			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Gastroenteritis Norovirus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Osteomyelitis Acute			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Staphylococcal Infection			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Folliculitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 November 2009	Collection of hematology and blood chemistry samples was added at week-12.
01 March 2011	1) The 300 U BOTOX dose group was removed from the protocol; 2) It was clarified that the latest time study treatment could be administered was week 144; and 3) It was clarified that the responder analysis included a cut-off of 100% and references to analysis of these data were removed, as the information from the responder analysis would be summarized only.
01 July 2012	Optional urodynamic assessments were to be done at sites that agreed to perform them and for those patients who agreed to undergo the procedure.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported