

**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
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**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:

<b>Subjects enrolled per age group</b>	
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
<b>Arm title</b>	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.

<b>Arm title</b>	Botulinum Toxin Type A 200U
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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.

<b>Number of subjects in period 1</b>	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 <sup>[1]</sup>
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 <sup>[2]</sup>
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**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).

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End point type	Primary
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**End point timeframe:**

Study Baseline, Week 6 Treatment Cycle 2

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**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

<b>End point values</b>	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)		

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**Statistical analyses**

No statistical analyses for this end point

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

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End point title	Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes <sup>[3]</sup>
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**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).

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End point type	Primary
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**End point timeframe:**

Study Baseline, Week 6 Treatment Cycle 3

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**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

<b>End point values</b>	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 <sup>[4]</sup>
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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
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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

<b>End point values</b>	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 <sup>[5]</sup>
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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
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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

<b>End point values</b>	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
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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
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End point timeframe:

Study Baseline, Week 6 Treatment Cycle 1

<b>End point values</b>	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
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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
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End point timeframe:

Study Baseline, Week 6 Treatment Cycle 2

<b>End point values</b>	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
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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
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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
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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
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End point timeframe:

Study Baseline, Week 6 Treatment Cycle 4

<b>End point values</b>	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
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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
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End point timeframe:

Study Baseline, Week 6 Treatment Cycle 5

<b>End point values</b>	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
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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
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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
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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
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End point timeframe:  
Study Baseline, Week 6 Treatment Cycle 4

<b>End point values</b>	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

<b>End point values</b>	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

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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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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### Reporting groups

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

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

<b>Serious adverse events</b>	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
<b>Respiratory, thoracic and mediastinal disorders</b>			
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
<b>Psychiatric disorders</b>			
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
<b>Concussion</b>			
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
<b>Fall</b>			
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
<b>Forearm Fracture</b>			
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
<b>Incisional Hernia</b>			
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
<b>Lower Limb Fracture</b>			
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
<b>Overdose</b>			
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
<b>Femur fracture</b>			
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
<b>Hip Fracture</b>			

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
<b>Ankle Fracture</b>			
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
<b>Cardiac disorders</b>			
<b>Myocardial Infarction</b>			
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
<b>Acute myocardial infarction</b>			
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
<b>Atrioventricular Block</b>			
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
<b>Angina Pectoris</b>			
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
<b>Atrial Fibrillation</b>			
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
<b>Arrhythmia</b>			
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
<b>Epilepsy</b>			
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
<b>Cervical myelopathy</b>			
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
<b>Spinal Cord Compression</b>			
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
<b>Syncope</b>			
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
<b>Blood and lymphatic system disorders</b>			
<b>Neutropenia</b>			
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
<b>Eye disorders</b>			
<b>Vision Blurred</b>			
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
<b>Gastrointestinal disorders</b>			
<b>Intestinal Obstruction</b>			

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
<b>Urethral Stenosis</b>			
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
<b>Nephrolithiasis</b>			
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
<b>Neurogenic Bladder</b>			
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
<b>Urinary Incontinence</b>			
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
<b>Hydronephrosis</b>			
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
<b>Hydroureter</b>			
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
<b>Endocrine disorders</b>			
<b>Hyperthyroidism</b>			
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
<b>Urosepsis</b>			
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
<b>Wound Infection</b>			
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
<b>Appendicitis</b>			
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
<b>Cellulitis</b>			
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
<b>Escherichia Sepsis</b>			
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
<b>Meningitis</b>			
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
<b>Necrotising Fasciitis</b>			
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
<b>Paronychia</b>			

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
<b>Sepsis</b>			
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
<b>Osteomyelitis</b>			
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
<b>Pyelonephritis Acute</b>			
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
<b>Systemic Candida</b>			
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
<b>Localised Infection</b>			
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
<b>Abscess of Salivary Gland</b>			
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
<b>Skin Infection</b>			
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
<b>Device Related Infection</b>			
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
<b>Bacteraemia</b>			
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
<b>Erysipelas</b>			
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
<b>Parotitis</b>			
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
<b>Viral Infection</b>			
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
<b>Post Procedural Infection</b>			
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
<b>Subcutaneous Abscess</b>			

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
<b>Metabolism and nutrition disorders</b>			
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

<b>Serious adverse events</b>	Botulinum Toxin Type A 200U Treatment Cycle 2	Botulinum Toxin Type A 300U Treatment Cycle 3	Botulinum Toxin Type A 200U Treatment Cycle 3
<b>Total subjects affected by serious adverse events</b>			
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
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
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
<b>Breast Cancer</b>			
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
<b>Squamous Cell Carcinoma</b>			
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
<b>Thyroid Neoplasm</b>			
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
<b>Squamous Cell Carcinoma of Skin</b>			
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
<b>Invasive Ductal Breast Carcinoma</b>			
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
<b>Glioblastoma</b>			
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
<b>Uterine Leiomyoma</b>			
	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
<b>Vascular disorders</b>			
<b>Hypertension</b>			

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
<b>Device Dislocation</b>			
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
<b>Oedema Peripheral</b>			
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
<b>Device Deployment Issue</b>			
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
<b>Impaired Healing</b>			
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
<b>Device Malfunction</b>			
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
<b>Immune system disorders</b>			
<b>Anaphylactic Reaction</b>			
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
<b>Reproductive system and breast disorders</b>			
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
<b>Psychiatric disorders</b>			
<b>Mental Status Changes</b>			
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
<b>Acute Psychosis</b>			
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
<b>Depression</b>			
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
<b>Confusional State</b>			
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
<b>Investigations</b>			
<b>Urine Cytology Abnormal</b>			
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
<b>Medical observation</b>			
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
<b>Injury, poisoning and procedural</b>			

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
<b>Femur fracture</b>			
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
<b>Hip Fracture</b>			
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
<b>Tibia Fracture</b>			
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
<b>Joint Dislocation</b>			
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
<b>Spinal Compression Fracture</b>			
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
<b>Scar</b>			
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
<b>Scrotal Haematoma</b>			
alternative assessment type: Non-systematic	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
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
<b>Atrial Fibrillation</b>			
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
<b>Arrhythmia</b>			
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
<b>Nervous system disorders</b>			
<b>Multiple Sclerosis Relapse</b>			
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
<b>Muscle Spasticity</b>			
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
<b>Cerebrovascular Accident</b>			
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
<b>Ischaemic Stroke</b>			
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
<b>Myasthenia Gravis</b>			

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
<b>Multiple Sclerosis</b>			
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
<b>Paraparesis</b>			
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
<b>Convulsion</b>			
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
<b>Epilepsy</b>			
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
<b>Cervical myelopathy</b>			
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
<b>Spinal Cord Compression</b>			
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
<b>Syncope</b>			
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
<b>Colitis Ischaemic</b>			
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
<b>Diarrhoea</b>			
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
<b>Haemorrhoidal Haemorrhage</b>			
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
<b>Large Intestine Perforation</b>			
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
<b>Lower Gastrointestinal Haemorrhage</b>			
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
<b>Melaena</b>			
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
<b>Small Intestinal Obstruction</b>			

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
<b>Stress Urinary Incontinence</b>			
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
<b>Bladder Neck Obstruction</b>			
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
<b>Haematuria</b>			
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
<b>Urethral Stenosis</b>			
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
<b>Nephrolithiasis</b>			
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
<b>Neurogenic Bladder</b>			
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
<b>Urinary Incontinence</b>			
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
<b>Back Pain</b>			
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
<b>Vertebral Foraminal Stenosis</b>			
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
<b>Bone Pain</b>			
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
<b>Lupus-Like Syndrome</b>			
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
<b>Costochondritis</b>			
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
<b>Exostosis</b>			
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
<b>Osteoarthritis</b>			
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
<b>Arthralgia</b>			
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
<b>Cervical Spinal Stenosis</b>			
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
<b>Rotator Cuff Syndrome</b>			
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
<b>Mobility Decreased</b>			
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
<b>Infections and infestations</b>			
<b>Urinary Tract Infection</b>			
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
<b>Pneumonia</b>			
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
<b>Clostridium Difficile Colitis</b>			

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
<b>Pyelonephritis</b>			
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
<b>Upper Respiratory Tract Infection alternative assessment type: Non-systematic</b>			
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
<b>Urinary Tract Infection Bacterial</b>			
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
<b>Urosepsis</b>			
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
<b>Wound Infection alternative assessment type: Non-systematic</b>			
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
<b>Appendicitis</b>			
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
<b>Cellulitis</b>			
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

<b>Serious adverse events</b>	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
<b>Glioblastoma</b>			
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
<b>Uterine Leiomyoma</b>	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
<b>Vascular disorders</b>			
<b>Hypertension</b>			
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
<b>Peripheral Ischaemia</b>			
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
<b>Deep Vein Thrombosis</b>			
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
<b>Peripheral Vascular Disorder</b>			
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
<b>Surgical and medical procedures</b>			
<b>Abortion Induced</b>	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
<b>General disorders and administration</b>			

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
<b>Immune system disorders</b>			
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
<b>Reproductive system and breast disorders</b>			
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
<b>Respiratory, thoracic and mediastinal disorders</b>			
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
<b>Pneumothorax</b>			
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
<b>Pulmonary Embolism</b>			
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
<b>Psychiatric disorders</b>			
<b>Mental Status Changes</b>			
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
<b>Acute Psychosis</b>			
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
<b>Depression</b>			
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
<b>Confusional State</b>			
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
<b>Investigations</b>			

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
<b>Myasthenia Gravis</b>			
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
<b>Multiple Sclerosis</b>			
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
<b>Paraparesis</b>			
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
<b>Convulsion</b>			
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
<b>Epilepsy</b>			
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
<b>Cervical myelopathy</b>			
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
<b>Spinal Cord Compression</b>			
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
<b>Syncope</b>			

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
<b>Blood and lymphatic system disorders</b>			
<b>Neutropenia</b>			
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
<b>Eye disorders</b>			
<b>Vision Blurred</b>			
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
<b>Gastrointestinal disorders</b>			
<b>Intestinal Obstruction</b>			
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
<b>Enterocolitis</b>			
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
<b>Umbilical Hernia</b>			
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
<b>Enterocutaneous Fistula</b>			
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
<b>Faecaloma</b>			

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
<b>Urethral Haemorrhage</b>			
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
<b>Stress Urinary Incontinence</b>			
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
<b>Bladder Neck Obstruction</b>			
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
<b>Haematuria</b>			
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
<b>Urethral Stenosis</b>			
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
<b>Nephrolithiasis</b>			
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
<b>Neurogenic Bladder</b>			
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
<b>Urinary Incontinence</b>			

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
<b>Muscular Weakness</b>			
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
<b>Back Pain</b>			
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
<b>Vertebral Foraminal Stenosis</b>			
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
<b>Bone Pain</b>			
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
<b>Lupus-Like Syndrome</b>			
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
<b>Costochondritis</b>			
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
<b>Exostosis</b>			

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
<b>Osteoarthritis</b>			
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
<b>Arthralgia</b>			
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
<b>Cervical Spinal Stenosis</b>			
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
<b>Rotator Cuff Syndrome</b>			
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
<b>Mobility Decreased</b>			
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
<b>Infections and infestations</b>			
<b>Urinary Tract Infection</b>			
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
<b>Systemic Candida</b>			
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
<b>Localised Infection</b>			
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
<b>Abscess of Salivary Gland</b>			
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
<b>Skin Infection</b>			
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
<b>Device Related Infection</b>			
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
<b>Bacteraemia</b>			
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
<b>Erysipelas</b>			

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
<b>Parotitis</b>			
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
<b>Viral Infection</b>			
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
<b>Post Procedural Infection</b>			
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
<b>Subcutaneous Abscess</b>			
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
<b>Metabolism and nutrition disorders</b>			
<b>Obesity</b>			
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
<b>Dehydration</b>			
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
<b>Hyperkalaemia</b>			

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

<b>Serious adverse events</b>	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
<b>Squamous Cell Carcinoma of Skin</b>			
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
<b>Invasive Ductal Breast Carcinoma</b>			
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
<b>Glioblastoma</b>			
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
<b>Uterine Leiomyoma</b>	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
<b>Vascular disorders</b>			
<b>Hypertension</b>			
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
<b>Peripheral Ischaemia</b>			
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
<b>Deep Vein Thrombosis</b>			
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
<b>Peripheral Vascular Disorder</b>			

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
<b>Surgical and medical procedures</b>			
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
<b>General disorders and administration site conditions</b>			
<b>Adverse Drug Reaction</b>			
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
<b>Non-Cardiac Chest Pain</b>			
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
<b>Pyrexia</b>			
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
<b>Device Dislocation</b>			
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
<b>Oedema Peripheral</b>			
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
<b>Device Deployment Issue</b>			

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
<b>Respiratory Failure</b>			
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
<b>Pneumonia Aspiration</b>			
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
<b>Pneumothorax</b>			
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
<b>Pulmonary Embolism</b>			
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
<b>Psychiatric disorders</b>			
<b>Mental Status Changes</b>			
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
<b>Acute Psychosis</b>			
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
<b>Depression</b>			
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
<b>Cerebrovascular Accident</b>			
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
<b>Ischaemic Stroke</b>			
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
<b>Myasthenia Gravis</b>			
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
<b>Multiple Sclerosis</b>			
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
<b>Paraparesis</b>			
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
<b>Convulsion</b>			
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
<b>Epilepsy</b>			
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
<b>Cervical myelopathy</b>			

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
<b>Spinal Cord Compression</b>			
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
<b>Syncope</b>			
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
<b>Blood and lymphatic system disorders</b>			
<b>Neutropenia</b>			
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
<b>Eye disorders</b>			
<b>Vision Blurred</b>			
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
<b>Gastrointestinal disorders</b>			
<b>Intestinal Obstruction</b>			
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
<b>Enterocolitis</b>			
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
<b>Umbilical Hernia</b>			

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
<b>Enterocutaneous Fistula</b>			
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
<b>Faecaloma</b>			
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
<b>Abdominal pain</b>			
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
<b>Colitis Ischaemic</b>			
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
<b>Diarrhoea</b>			
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
<b>Haemorrhoidal Haemorrhage</b>			
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
<b>Large Intestine Perforation</b>			

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
<b>Skin and subcutaneous tissue disorders</b>			
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
<b>Renal and urinary disorders</b>			
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
<b>Nephrolithiasis</b>			
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
<b>Neurogenic Bladder</b>			
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
<b>Urinary Incontinence</b> 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
<b>Hydronephrosis</b>			
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
<b>Hydroureter</b>			
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
<b>Endocrine disorders</b>			
<b>Hyperthyroidism</b>			
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
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Lumbar Spinal Stenosis</b>			

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
<b>Spondylolisthesis</b>			
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
<b>Foot Deformity</b>			
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
<b>Intervertebral Disc Protrusion</b>			
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
<b>Muscular Weakness</b>			
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
<b>Back Pain</b>			
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
<b>Vertebral Foraminal Stenosis</b>			
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
<b>Bone Pain</b>			
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
<b>Urosepsis</b>			
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
<b>Wound Infection</b>			
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
<b>Appendicitis</b>			
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
<b>Cellulitis</b>			
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
<b>Escherichia Sepsis</b>			
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
<b>Meningitis</b>			
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
<b>Necrotising Fasciitis</b>			
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
<b>Paronychia</b>			

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
<b>Sepsis</b>			
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
<b>Osteomyelitis</b>			
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
<b>Pyelonephritis Acute</b>			
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
<b>Systemic Candida</b>			
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
<b>Localised Infection</b>			
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
<b>Abscess of Salivary Gland</b>			
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
<b>Skin Infection</b>			
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
<b>Device Related Infection</b>			
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
<b>Bacteraemia</b>			
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
<b>Erysipelas</b>			
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
<b>Parotitis</b>			
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
<b>Viral Infection</b>			
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
<b>Post Procedural Infection</b>			
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
<b>Subcutaneous Abscess</b>			

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
<b>Metabolism and nutrition disorders</b>			
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

<b>Serious adverse events</b>	Botulinum Toxin Type A 300U Treatment Cycle 7	Botulinum Toxin Type A 200U Treatment Cycle 7	Botulinum Toxin Type A 200U Treatment Cycle 8
<b>Total subjects affected by serious adverse events</b>			
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
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
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
<b>Breast Cancer</b>			
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
<b>Squamous Cell Carcinoma</b>			
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
<b>Thyroid Neoplasm</b>			
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
<b>Squamous Cell Carcinoma of Skin</b>			
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
<b>Invasive Ductal Breast Carcinoma</b>			
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
<b>Glioblastoma</b>			
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
<b>Uterine Leiomyoma</b>	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
<b>Vascular disorders</b>			
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
<b>Psychiatric disorders</b>			
<b>Mental Status Changes</b>			
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
<b>Acute Psychosis</b>			
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
<b>Depression</b>			
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
<b>Confusional State</b>			
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
<b>Investigations</b>			
<b>Urine Cytology Abnormal</b>			
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
<b>Medical observation</b>			
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
<b>Injury, poisoning and procedural</b>			

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			
alternative assessment type: Non-systematic	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
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
<b>Atrial Fibrillation</b>			
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
<b>Arrhythmia</b>			
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
<b>Nervous system disorders</b>			
<b>Multiple Sclerosis Relapse</b>			
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
<b>Muscle Spasticity</b>			
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
<b>Cerebrovascular Accident</b>			
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
<b>Ischaemic Stroke</b>			
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
<b>Myasthenia Gravis</b>			

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
<b>Multiple Sclerosis</b>			
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
<b>Paraparesis</b>			
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
<b>Convulsion</b>			
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
<b>Epilepsy</b>			
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
<b>Cervical myelopathy</b>			
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
<b>Spinal Cord Compression</b>			
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
<b>Syncope</b>			
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
<b>Colitis Ischaemic</b>			
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
<b>Diarrhoea</b>			
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
<b>Haemorrhoidal Haemorrhage</b>			
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
<b>Large Intestine Perforation</b>			
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
<b>Lower Gastrointestinal Haemorrhage</b>			
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
<b>Melaena</b>			
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
<b>Small Intestinal Obstruction</b>			

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
<b>Stress Urinary Incontinence</b>			
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
<b>Bladder Neck Obstruction</b>			
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
<b>Haematuria</b>			
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
<b>Urethral Stenosis</b>			
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
<b>Nephrolithiasis</b>			
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
<b>Neurogenic Bladder</b>			
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
<b>Urinary Incontinence</b>			
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
<b>Back Pain</b>			
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
<b>Vertebral Foraminal Stenosis</b>			
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
<b>Bone Pain</b>			
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
<b>Lupus-Like Syndrome</b>			
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
<b>Costochondritis</b>			
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
<b>Exostosis</b>			
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
<b>Osteoarthritis</b>			
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
<b>Pyelonephritis</b>			
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
<b>Upper Respiratory Tract Infection alternative assessment type: Non-systematic</b>			
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
<b>Urinary Tract Infection Bacterial</b>			
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
<b>Urosepsis</b>			
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
<b>Wound Infection alternative assessment type: Non-systematic</b>			
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
<b>Appendicitis</b>			
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
<b>Cellulitis</b>			
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

<b>Serious adverse events</b>	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
<b>Glioblastoma</b>			
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
<b>Uterine Leiomyoma</b>	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
<b>Vascular disorders</b>			
<b>Hypertension</b>			
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
<b>Peripheral Ischaemia</b>			
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
<b>Deep Vein Thrombosis</b>			
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
<b>Peripheral Vascular Disorder</b>			
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
<b>Surgical and medical procedures</b>			
<b>Abortion Induced</b>	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
<b>General disorders and administration</b>			

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
<b>Immune system disorders</b>			
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
<b>Reproductive system and breast disorders</b>			
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
<b>Respiratory, thoracic and mediastinal disorders</b>			
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
<b>Pneumothorax</b>			
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
<b>Pulmonary Embolism</b>			
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
<b>Psychiatric disorders</b>			
<b>Mental Status Changes</b>			
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
<b>Acute Psychosis</b>			
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
<b>Depression</b>			
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
<b>Confusional State</b>			
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
<b>Investigations</b>			

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
<b>Myasthenia Gravis</b>			
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
<b>Multiple Sclerosis</b>			
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
<b>Paraparesis</b>			
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
<b>Convulsion</b>			
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
<b>Epilepsy</b>			
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
<b>Cervical myelopathy</b>			
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
<b>Spinal Cord Compression</b>			
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
<b>Syncope</b>			

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
<b>Blood and lymphatic system disorders</b>			
<b>Neutropenia</b>			
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
<b>Eye disorders</b>			
<b>Vision Blurred</b>			
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
<b>Gastrointestinal disorders</b>			
<b>Intestinal Obstruction</b>			
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
<b>Enterocolitis</b>			
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
<b>Umbilical Hernia</b>			
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
<b>Enterocutaneous Fistula</b>			
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
<b>Faecaloma</b>			

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
<b>Urethral Haemorrhage</b>			
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
<b>Stress Urinary Incontinence</b>			
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
<b>Bladder Neck Obstruction</b>			
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
<b>Haematuria</b>			
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
<b>Urethral Stenosis</b>			
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
<b>Nephrolithiasis</b>			
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
<b>Neurogenic Bladder</b>			
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
<b>Urinary Incontinence</b>			

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
<b>Muscular Weakness</b>			
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
<b>Back Pain</b>			
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
<b>Vertebral Foraminal Stenosis</b>			
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
<b>Bone Pain</b>			
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
<b>Lupus-Like Syndrome</b>			
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
<b>Costochondritis</b>			
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
<b>Exostosis</b>			

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
<b>Osteoarthritis</b>			
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
<b>Arthralgia</b>			
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
<b>Cervical Spinal Stenosis</b>			
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
<b>Rotator Cuff Syndrome</b>			
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
<b>Mobility Decreased</b>			
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
<b>Infections and infestations</b>			
<b>Urinary Tract Infection</b>			
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
<b>Systemic Candida</b>			
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
<b>Localised Infection</b>			
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
<b>Abscess of Salivary Gland</b>			
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
<b>Skin Infection</b>			
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
<b>Device Related Infection</b>			
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
<b>Bacteraemia</b>			
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
<b>Erysipelas</b>			

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
<b>Parotitis</b>			
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
<b>Viral Infection</b>			
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
<b>Post Procedural Infection</b>			
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
<b>Subcutaneous Abscess</b>			
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
<b>Metabolism and nutrition disorders</b>			
<b>Obesity</b>			
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
<b>Dehydration</b>			
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
<b>Hyperkalaemia</b>			

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
<b>Hypoglycaemia</b>			
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

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

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		
<b>Surgical and medical procedures</b>			
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		
<b>General disorders and administration site conditions</b>			
<b>Adverse Drug Reaction</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Non-Cardiac Chest Pain</b>			
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		
<b>Pyrexia</b>			
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		
<b>Device Dislocation</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Oedema Peripheral</b>			
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		
<b>Device Deployment Issue</b>			

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		
<b>Respiratory Failure</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pneumonia Aspiration</b>			
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		
<b>Pneumothorax</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Pulmonary Embolism</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Psychiatric disorders</b>			
<b>Mental Status Changes</b>			
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		
<b>Acute Psychosis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Depression</b>			
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		
<b>Confusional State</b>			
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		
<b>Investigations</b>			
<b>Urine Cytology Abnormal</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Medical observation</b>			
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		
<b>Injury, poisoning and procedural complications</b>			
<b>Craniocerebral Injury</b>			
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		
<b>Tendon Rupture</b>			
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		
<b>Concussion</b>			
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		
<b>Cerebrovascular Accident</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Ischaemic Stroke</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Myasthenia Gravis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Multiple Sclerosis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Paraparesis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Convulsion</b>			
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		
<b>Epilepsy</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cervical myelopathy</b>			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Spinal Cord Compression</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Syncope</b>			
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		
<b>Blood and lymphatic system disorders</b>			
<b>Neutropenia</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Eye disorders</b>			
<b>Vision Blurred</b>			
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		
<b>Gastrointestinal disorders</b>			
<b>Intestinal Obstruction</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Enterocolitis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Umbilical Hernia</b>			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Enterocutaneous Fistula</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Faecaloma</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Abdominal pain</b>			
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		
<b>Colitis Ischaemic</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Diarrhoea</b>			
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		
<b>Haemorrhoidal Haemorrhage</b>			
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		
<b>Large Intestine Perforation</b>			

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		
<b>Skin and subcutaneous tissue disorders</b>			
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		
<b>Renal and urinary disorders</b>			
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		
<b>Nephrolithiasis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Neurogenic Bladder</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Urinary Incontinence</b>			
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		
<b>Hydronephrosis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hydroureter</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Endocrine disorders</b>			
<b>Hyperthyroidism</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Lumbar Spinal Stenosis</b>			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Spondylolisthesis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Foot Deformity</b>			
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		
<b>Intervertebral Disc Protrusion</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Muscular Weakness</b>			
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		
<b>Back Pain</b>			
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		
<b>Vertebral Foraminal Stenosis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bone Pain</b>			
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		
<b>Lupus-Like Syndrome</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Costochondritis</b>			
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		
<b>Exostosis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Osteoarthritis</b>			
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		
<b>Arthralgia</b>			
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		
<b>Cervical Spinal Stenosis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Rotator Cuff Syndrome</b>			
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		
<b>Urosepsis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Wound Infection</b>			
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		
<b>Appendicitis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Cellulitis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Escherichia Sepsis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Meningitis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Necrotising Fasciitis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Paronychia</b>			

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		
<b>Device Related Infection</b>			
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		
<b>Bacteraemia</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Erysipelas</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Parotitis</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Viral Infection</b>			
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		
<b>Post Procedural Infection</b>			
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		
<b>Subcutaneous Abscess</b>			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Metabolism and nutrition disorders</b>			
<b>Obesity</b>			
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		
<b>Dehydration</b>			
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		
<b>Hyperkalaemia</b>			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Hypoglycaemia</b>			
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 %

<b>Non-serious adverse events</b>	Botulinum Toxin Type A 300U Treatment Cycle 1	Botulinum Toxin Type A 200U Treatment Cycle 1	Botulinum Toxin Type A 300U Treatment Cycle 2
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	154 / 185 (83.24%)	170 / 203 (83.74%)	126 / 163 (77.30%)
<b>General disorders and administration site conditions</b>			
<b>Oedema Peripheral</b>			
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 occurrences (all)	6 / 185 (3.24%) 8	13 / 203 (6.40%) 14	4 / 163 (2.45%) 4
Pyrexia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	4 / 185 (2.16%) 4	17 / 203 (8.37%) 19	5 / 163 (3.07%) 6
Reproductive system and breast disorders			
Ovarian Cyst subjects affected / exposed occurrences (all)	0 / 185 (0.00%) 0	0 / 203 (0.00%) 0	0 / 163 (0.00%) 0
Vulvovaginal Pruritus alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 185 (0.00%) 0	1 / 203 (0.49%) 3	0 / 163 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Rhinitis Seasonal alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 185 (0.00%) 0	0 / 203 (0.00%) 0	0 / 163 (0.00%) 0
Psychiatric disorders			
Depression alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	5 / 185 (2.70%) 6	6 / 203 (2.96%) 6	3 / 163 (1.84%) 4
Investigations			
Expanded Disability Status Scale Score Increased subjects affected / exposed occurrences (all)	7 / 185 (3.78%) 9	10 / 203 (4.93%) 10	13 / 163 (7.98%) 14
Haemoglobin Decreased subjects affected / exposed occurrences (all)	0 / 185 (0.00%) 0	0 / 203 (0.00%) 0	0 / 163 (0.00%) 0
Central Nervous System Function Test Abnormal			

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

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

Additional description: Females Only

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
<b>Herpes Zoster</b>			
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
<b>Fungal Skin Infection</b>			
subjects affected / exposed	1 / 185 (0.54%)	2 / 203 (0.99%)	0 / 163 (0.00%)
occurrences (all)	1	2	0
<b>Gastroenteritis Norovirus</b>			
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
<b>Osteomyelitis Acute</b>			
subjects affected / exposed	0 / 185 (0.00%)	0 / 203 (0.00%)	0 / 163 (0.00%)
occurrences (all)	0	0	0
<b>Staphylococcal Infection</b>			
subjects affected / exposed	0 / 185 (0.00%)	1 / 203 (0.49%)	0 / 163 (0.00%)
occurrences (all)	0	1	0
<b>Folliculitis</b>			
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

<b>Non-serious adverse events</b>	<b>Botulinum Toxin Type A 200U Treatment Cycle 2</b>	<b>Botulinum Toxin Type A 300U Treatment Cycle 3</b>	<b>Botulinum Toxin Type A 200U Treatment Cycle 3</b>
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	147 / 187 (78.61%)	89 / 119 (74.79%)	123 / 175 (70.29%)
<b>General disorders and administration site conditions</b>			
<b>Oedema Peripheral</b>			
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
<b>Fatigue</b>			
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 occurrences (all)	0 / 187 (0.00%) 0	0 / 119 (0.00%) 0	0 / 175 (0.00%) 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 occurrences (all)	1 / 187 (0.53%) 1	0 / 119 (0.00%) 0	1 / 175 (0.57%) 1
Gastrointestinal disorders Diarrhoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Vomiting alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Nausea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Constipation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	6 / 187 (3.21%) 6  2 / 187 (1.07%) 2  2 / 187 (1.07%) 2  5 / 187 (2.67%) 6	3 / 119 (2.52%) 3  1 / 119 (0.84%) 1  3 / 119 (2.52%) 3  5 / 119 (4.20%) 5	1 / 175 (0.57%) 1  4 / 175 (2.29%) 5  1 / 175 (0.57%) 1  4 / 175 (2.29%) 4
Skin and subcutaneous tissue disorders Dermatitis Atopic alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Rash alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 187 (0.00%) 0  2 / 187 (1.07%) 2	0 / 119 (0.00%) 0  0 / 119 (0.00%) 0	0 / 175 (0.00%) 0  1 / 175 (0.57%) 1
Renal and urinary disorders Urinary Retention alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Pollakiuria	15 / 187 (8.02%) 15	8 / 119 (6.72%) 9	11 / 175 (6.29%) 11

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

Additional description: Females Only

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
<b>Herpes Zoster</b>			
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
<b>Fungal Skin Infection</b>			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	1 / 175 (0.57%)
occurrences (all)	0	0	1
<b>Gastroenteritis Norovirus</b>			
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
<b>Osteomyelitis Acute</b>			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
<b>Staphylococcal Infection</b>			
subjects affected / exposed	0 / 187 (0.00%)	0 / 119 (0.00%)	0 / 175 (0.00%)
occurrences (all)	0	0	0
<b>Folliculitis</b>			
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

<b>Non-serious adverse events</b>	<b>Botulinum Toxin Type A 300U Treatment Cycle 4</b>	<b>Botulinum Toxin Type A 200U Treatment Cycle 4</b>	<b>Botulinum Toxin Type A 300U Treatment Cycle 5</b>
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	51 / 69 (73.91%)	109 / 153 (71.24%)	19 / 34 (55.88%)
<b>General disorders and administration site conditions</b>			
<b>Oedema Peripheral</b>			
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
<b>Fatigue</b>			
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 occurrences (all)	0 / 69 (0.00%) 0	0 / 153 (0.00%) 0	0 / 34 (0.00%) 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 occurrences (all)	0 / 69 (0.00%) 0	0 / 153 (0.00%) 0	1 / 34 (2.94%) 1
Gastrointestinal disorders Diarrhoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	3 / 69 (4.35%) 3	4 / 153 (2.61%) 5	2 / 34 (5.88%) 2
Vomiting alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 69 (1.45%) 1	2 / 153 (1.31%) 2	1 / 34 (2.94%) 1
Nausea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 69 (1.45%) 2	1 / 153 (0.65%) 1	0 / 34 (0.00%) 0
Constipation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 69 (1.45%) 1	7 / 153 (4.58%) 8	0 / 34 (0.00%) 0
Skin and subcutaneous tissue disorders Dermatitis Atopic alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 69 (0.00%) 0	0 / 153 (0.00%) 0	0 / 34 (0.00%) 0
Rash alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 69 (1.45%) 1	0 / 153 (0.00%) 0	0 / 34 (0.00%) 0
Renal and urinary disorders Urinary Retention alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 69 (0.00%) 0	4 / 153 (2.61%) 4	0 / 34 (0.00%) 0
Pollakiuria			

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

Additional description: Females Only

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
<b>Herpes Zoster</b>			
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
<b>Fungal Skin Infection</b>			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
<b>Gastroenteritis Norovirus</b>			
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
<b>Osteomyelitis Acute</b>			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
<b>Staphylococcal Infection</b>			
subjects affected / exposed	0 / 69 (0.00%)	0 / 153 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
<b>Folliculitis</b>			
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

<b>Non-serious adverse events</b>	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%)
<b>General disorders and administration site conditions</b>			
<b>Oedema Peripheral</b>			
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
<b>Fatigue</b>			
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 occurrences (all)	0 / 110 (0.00%) 0	0 / 16 (0.00%) 0	0 / 70 (0.00%) 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 occurrences (all)	0 / 110 (0.00%) 0	0 / 16 (0.00%) 0	1 / 70 (1.43%) 1
Gastrointestinal disorders Diarrhoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Vomiting alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Nausea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Constipation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	4 / 110 (3.64%) 4  3 / 110 (2.73%) 4  3 / 110 (2.73%) 3  4 / 110 (3.64%) 5	0 / 16 (0.00%) 0  1 / 16 (6.25%) 1  1 / 16 (6.25%) 1  0 / 16 (0.00%) 0	4 / 70 (5.71%) 5  2 / 70 (2.86%) 2  1 / 70 (1.43%) 1  1 / 70 (1.43%) 1
Skin and subcutaneous tissue disorders Dermatitis Atopic alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Rash alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 110 (0.00%) 0  1 / 110 (0.91%) 1	0 / 16 (0.00%) 0  0 / 16 (0.00%) 0	0 / 70 (0.00%) 0  1 / 70 (1.43%) 1
Renal and urinary disorders Urinary Retention alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Pollakiuria	2 / 110 (1.82%) 3	0 / 16 (0.00%) 0	0 / 70 (0.00%) 0

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

Additional description: Females Only

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
<b>Herpes Zoster</b>			
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
<b>Fungal Skin Infection</b>			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
<b>Gastroenteritis Norovirus</b>			
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
<b>Osteomyelitis Acute</b>			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
<b>Staphylococcal Infection</b>			
subjects affected / exposed	0 / 110 (0.00%)	0 / 16 (0.00%)	0 / 70 (0.00%)
occurrences (all)	0	0	0
<b>Folliculitis</b>			
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

<b>Non-serious adverse events</b>	<b>Botulinum Toxin Type A 300U Treatment Cycle 7</b>	<b>Botulinum Toxin Type A 200U Treatment Cycle 7</b>	<b>Botulinum Toxin Type A 200U Treatment Cycle 8</b>
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	3 / 8 (37.50%)	28 / 48 (58.33%)	23 / 36 (63.89%)
<b>General disorders and administration site conditions</b>			
<b>Oedema Peripheral</b>			
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
<b>Fatigue</b>			
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 occurrences (all)	0 / 8 (0.00%) 0	0 / 48 (0.00%) 0	0 / 36 (0.00%) 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 occurrences (all)	0 / 8 (0.00%) 0	0 / 48 (0.00%) 0	0 / 36 (0.00%) 0
Gastrointestinal disorders Diarrhoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Vomiting alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Nausea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Constipation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0  0 / 8 (0.00%) 0  0 / 8 (0.00%) 0  0 / 8 (0.00%) 0  0 / 8 (0.00%) 0	3 / 48 (6.25%) 4  0 / 48 (0.00%) 0  1 / 48 (2.08%) 1  3 / 48 (6.25%) 3	0 / 36 (0.00%) 0  1 / 36 (2.78%) 2  1 / 36 (2.78%) 2  1 / 36 (2.78%) 1
Skin and subcutaneous tissue disorders Dermatitis Atopic alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Rash alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0  0 / 8 (0.00%) 0	0 / 48 (0.00%) 0  1 / 48 (2.08%) 1	0 / 36 (0.00%) 0  1 / 36 (2.78%) 1
Renal and urinary disorders Urinary Retention alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Pollakiuria	0 / 8 (0.00%) 0	0 / 48 (0.00%) 0	0 / 36 (0.00%) 0

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

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
<b>Herpes Zoster</b>			
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
<b>Fungal Skin Infection</b>			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
<b>Gastroenteritis Norovirus</b>			
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
<b>Osteomyelitis Acute</b>			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
<b>Staphylococcal Infection</b>			
subjects affected / exposed	0 / 8 (0.00%)	0 / 48 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
<b>Folliculitis</b>			
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

<b>Non-serious adverse events</b>	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%)
<b>General disorders and administration site conditions</b>			
<b>Oedema Peripheral</b>			
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
<b>Fatigue</b>			
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 occurrences (all)	0 / 22 (0.00%) 0	1 / 11 (9.09%) 1	0 / 5 (0.00%) 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 occurrences (all)	0 / 22 (0.00%) 0	1 / 11 (9.09%) 1	0 / 5 (0.00%) 0
Gastrointestinal disorders Diarrhoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Vomiting alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Nausea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Constipation alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0  0 / 22 (0.00%) 0  0 / 22 (0.00%) 0  0 / 22 (0.00%) 0	0 / 11 (0.00%) 0  0 / 11 (0.00%) 0  0 / 11 (0.00%) 0  0 / 11 (0.00%) 0	0 / 5 (0.00%) 0  0 / 5 (0.00%) 0  0 / 5 (0.00%) 0  0 / 5 (0.00%) 0
Skin and subcutaneous tissue disorders Dermatitis Atopic alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Rash alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0  0 / 22 (0.00%) 0	1 / 11 (9.09%) 1  1 / 11 (9.09%) 1	0 / 5 (0.00%) 0  0 / 5 (0.00%) 0
Renal and urinary disorders Urinary Retention alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Pollakiuria	0 / 22 (0.00%) 0	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0

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

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
<b>Herpes Zoster</b>			
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
<b>Fungal Skin Infection</b>			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
<b>Gastroenteritis Norovirus</b>			
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
<b>Osteomyelitis Acute</b>			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
<b>Staphylococcal Infection</b>			
subjects affected / exposed	0 / 22 (0.00%)	1 / 11 (9.09%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
<b>Folliculitis</b>			
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

<b>Non-serious adverse events</b>	Botulinum Toxin Type A 200U Treatment Cycle 12		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)		
<b>General disorders and administration site conditions</b>			
<b>Oedema Peripheral</b>			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
<b>Fatigue</b>			
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 occurrences (all)	0 / 2 (0.00%) 0		
Injury, poisoning and procedural complications Fall alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Muscle Strain alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Hand Fracture subjects affected / exposed occurrences (all)  Contusion subjects affected / exposed occurrences (all)  Thermal Burn alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0  0 / 2 (0.00%) 0  0 / 2 (0.00%) 0  0 / 2 (0.00%) 0  0 / 2 (0.00%) 0		
Cardiac disorders Bundle Branch Block Right subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Nervous system disorders Muscle Spasticity alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)  Headache alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0  0 / 2 (0.00%) 0		
Blood and lymphatic system disorders			

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

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

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

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported