Clinical trial results:
BGOG-OV5:Phase II study of weekly Paclitaxel/Carboplatin in combination with prophylactic G-CSF in the treatment of gynaecological cancers.

Summary

EudraCT number	2010-022482-95
Trial protocol	BE
Global end of trial date	14 August 2018

Results information

Result version number	v1 (current)
This version publication date	26 March 2021
First version publication date	26 March 2021
Summary attachment (see zip file)	Summary (BGOG-ov5 Prot Synopsis En v1.0.pdf)

Trial information

Trial identification

Sponsor protocol code	BGOG-ov-5

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Belgian Gynaecological Oncology Group
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Ignace Vergote, Belgian Gynaecological Oncology Group (BGOG), bgog@engot.eu
Scientific contact	Ignace Vergote, Belgian Gynaecological Oncology Group (BGOG), 0032 16347419, ignace.vergote@uzleuven.be

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	09 May 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 August 2013
Global end of trial reached?	Yes
Global end of trial date	14 August 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

*to evaluate occurrence of grade 4 neutropenia during weekly paclitaxel/carboplatin with prophylactic G-CSF

Protection of trial subjects:

Weekly monitoring adverse events - Hematology monitoring
3 weekly physical exams
CT/MRI abdomen/thorax/pelvis

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 January 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 108
Worldwide total number of subjects	108
EEA total number of subjects	108

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	64
From 65 to 84 years	44

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

FPI: 21-feb-2012
LPI: 27-mrt-2013

Pre-assignment

Screening details:

Screening criteria:
- female over 18 years
- ECOG 0-2
- Adequate organ function
- Measurable disease

Ovarian cohort:
- invasive epithelial ovarian, fallopian tube or peritoneal carcninoma
- 1 earlier platin treatment. Platin refractory

Endometrium/cervical cohort:
- Endometrial/ cervical carcinoma
- recurrent or advanced

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Overall trial
Arm description: -	
Arm type	Single arm
Investigational medicinal product name	Filgastrim
Investigational medicinal product code	
Other name	Neupogen
Pharmaceutical forms	Suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Filgastrim 30 Mio U (0.600 mg/ml) for patients weighing less than 60kg
Filgastrim 48 Mio U 0.5ml (0.960 mg/ml) for patients wieghing more than 60 kg

Given on day 5 of each course.
Courses will be repeated 18 times weekly except for course 10, which will be given 2 weeks after course 9

Number of subjects in period 1	Overall trial
Started	108
Completed	108

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	108	108	
Age categorical Units: Subjects			
Adults (18-64 years)	64	64	
From 65-84 years	44	44	
85 years and over	0	0	
Age continuous Units: years			
median	60.2		
standard deviation	± 12.28	-	
Gender categorical Units: Subjects			
Female	108	108	
Male	0	0	

Subject analysis sets	
Subject analysis set title	Overall trial
Subject analysis set type	Full analysis
Subject analysis set description: All patients participating in the trial	
Subject analysis set title	Endometrium
Subject analysis set type	Sub-group analysis
Subject analysis set description: Endometrial cancer cohort	
Subject analysis set title	Ovarian
Subject analysis set type	Sub-group analysis
Subject analysis set description: Ovarian, fallopian tube and peritoneal carcinoma cohort	
Subject analysis set title	Cervix
Subject analysis set type	Sub-group analysis
Subject analysis set description: Cervical carcinoma cohort	

Reporting group values	Overall trial	Endometrium	Ovarian
Number of subjects	108	36	36
Age categorical Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
85 years and over			

Age continuous Units: years			
median	60.2	66.4	62.6
standard deviation	± 12.28	± 9.86	± 10.48
Gender categorical Units: Subjects			
Female			
Male			

Reporting group values	Cervix		
Number of subjects	36		
Age categorical Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
median	51.3		
standard deviation	± 11.43		
Gender categorical Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Overall trial
Reporting group description: -	
Subject analysis set title	Overall trial
Subject analysis set type	Full analysis
Subject analysis set description: All patients participating in the trial	
Subject analysis set title	Endometrium
Subject analysis set type	Sub-group analysis
Subject analysis set description: Endometrial cancer cohort	
Subject analysis set title	Ovarian
Subject analysis set type	Sub-group analysis
Subject analysis set description: Ovarian, fallopian tube and peritoneal carcinoma cohort	
Subject analysis set title	Cervix
Subject analysis set type	Sub-group analysis
Subject analysis set description: Cervical carcinoma cohort	

Primary: Overall Grade 3/4 neutrophenia

End point title	Overall Grade 3/4 neutrophenia[1]
End point description: Patients were scored positive on Grade 3/4 neutrophenia if they had at least one AE specified as 'Neutrophil count decreased' in combination with a severity level equal to 3 or 4.	
End point type	Primary
End point timeframe: Overall trial period	

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 comparison between different groups were possible for the overall trial. The overall number en proportion of patients with grade 3/4 neutropenia were compared with historical data. A formal test shows that the occurence of grade3/4 neutropenia is lower compared to historical data (84%)

End point values	Overall trial			
Subject group type	Subject analysis set			
Number of subjects analysed	102			
Units: Grade 3/4 neutropenia				
number (confidence interval 95%)	0.343 (0.258 to 0.439)			

Statistical analyses

No statistical analyses for this end point

Secondary: Grade 3/4 neutropenia cohort

End point title	Grade 3/4 neutropenia cohort

End point description:

End point type	Secondary

End point timeframe:

Overall trial period

End point values	Endometrium	Ovarian	Cervix	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	33	35	34	
Units: Grade 3/4 neutropenia				
number (confidence interval 95%)	0.364 (0.222 to 0.534)	0.286 (0.163 to 0.451)	0.382 (0.239 to 0.550)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response rate (CR+PR)

End point title	Overall Response rate (CR+PR)

End point description:

End point type	Secondary

End point timeframe:

Overall trial

End point values	Overall trial			
Subject group type	Subject analysis set			
Number of subjects analysed	93			
Units: Patients				
number (confidence interval 95%)	0.505 (0.406 to 0.605)			

Statistical analyses

No statistical analyses for this end point

Secondary: Confirmed response rate (CR+PR)

End point title	Confirmed response rate (CR+PR)

End point description:

End point type	Secondary

End point timeframe:
Overall trial

End point values	Overall trial			
Subject group type	Subject analysis set			
Number of subjects analysed	93			
Units: Patients				
number (confidence interval 95%)	0.280 (0.199 to 0.378)			

Statistical analyses

No statistical analyses for this end point

Secondary: Unconfirmed response rate (CR+PR)

End point title	Unconfirmed response rate (CR+PR)

End point description:

End point type	Secondary

End point timeframe:
Overall trial

End point values	Overall trial			
Subject group type	Subject analysis set			
Number of subjects analysed	93			
Units: Patients				
number (confidence interval 95%)	0.226 (0.153 to 0.321)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall response rate (CR+PR) cohort

End point title	Overall response rate (CR+PR) cohort

End point description:

End point type	Secondary

End point timeframe:
Overall trial

End point values	Endometrium	Ovarian	Cervix	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	29	31	33	
Units: Patients				
number (confidence interval 95%)	0.448 (0.284 to 0.625)	0.484 (0.320 to 0.652)	0.576 (0.408 to 0.728)	

Statistical analyses

No statistical analyses for this end point

Secondary: Confirmed response rate (CR+PR) cohort

End point title	Confirmed response rate (CR+PR) cohort

End point description:

End point type	Secondary

End point timeframe:
Overall trial

End point values	Endometrium	Ovarian	Cervix	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	29	31	33	
Units: Patients				
number (confidence interval 95%)	0.207 (0.098 to 0.384)	0.290 (0.161 to 0.466)	0.333 (0.198 to 0.504)	

Statistical analyses

No statistical analyses for this end point

Secondary: Unconfirmed reponse rate (CR+PR) cohort

End point title	Unconfirmed reponse rate (CR+PR) cohort

End point description:

End point type	Secondary

End point timeframe:
Overall trial

End point values	Endometrium	Ovarian	Cervix	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	29	31	33	
Units: Patients				
number (confidence interval 95%)	0.241 (0.122 to 0.421)	0.194 (0.092 to 0.363)	0.242 (0.128 to 0.410)	

Statistical analyses

No statistical analyses for this end point

Secondary: Median overall survival

End point title	Median overall survival

End point description:

End point type	Secondary

End point timeframe:

Overall trial

End point values	Overall trial			
Subject group type	Subject analysis set			
Number of subjects analysed	102			
Units: Months				
median (confidence interval 95%)	12.70 (10.23 to 16.25)			

Statistical analyses

No statistical analyses for this end point

Secondary: Median overall survival cohort

End point title	Median overall survival cohort

End point description:

End point type	Secondary

End point timeframe:

Overall trial

End point values	Endometrium	Ovarian	Cervix	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	33	35	34	
Units: months				
median (confidence interval 95%)	18.52 (7.70 to 99999)	12.66 (8.42 to 19.21)	13.62 (10.13 to 16.25)	

Statistical analyses

No statistical analyses for this end point

Secondary: Median Progression Free Survival

End point title	Median Progression Free Survival

End point description:

End point type	Secondary

End point timeframe:

Overall trial

End point values	Overall trial	Endometrium	Ovarian	Cervix
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	102	33	35	34
Units: Months				
median (confidence interval 95%)	7.14 (5.13 to 8.09)	5.66 (3.95 to 8.55)	7.47 (5.79 to 8.39)	5.69 (4.38 to 10.26)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Overall trial	
Assessment type	Systematic
Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.03
Reporting groups	
Reporting group title	Overall trial
Reporting group description: -	
Reporting group title	Ovarium Cancer
Reporting group description: -	
Reporting group title	Endometrium
Reporting group description: -	
Reporting group title	Cervix
Reporting group description: -	

Serious adverse events	Overall trial	Ovarium Cancer	Endometrium
Total subjects affected by serious adverse events			
subjects affected / exposed	42 / 108 (38.89%)	14 / 36 (38.89%)	14 / 36 (38.89%)
number of deaths (all causes)	11	5	5
number of deaths resulting from adverse events	3	0	3
Vascular disorders			
Thromboembolitic event			
subjects affected / exposed	3 / 108 (2.78%)	1 / 36 (2.78%)	2 / 36 (5.56%)
occurrences causally related to treatment / all	1 / 3	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Colostomy problems			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	3 / 108 (2.78%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1

Fever			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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
General Weakness			
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	1 / 2	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (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
Social circumstances			
Social problem			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Reproductive system and breast disorders			
Vaginal pain			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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 pain			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (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
Respiratory failure			

subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Investigations			
Neutrophil count decreased			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	4 / 108 (3.70%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	5 / 5	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fracture			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angor			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			

subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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
Obstruction			
subjects affected / exposed	5 / 108 (4.63%)	2 / 36 (5.56%)	2 / 36 (5.56%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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
Haemorrhage			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Fistula of small intestine			

subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Ileus			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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
Fistula	Additional description: ileo-vaginal-bladder fistula		
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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
Skin and subcutaneous tissue disorders			
Erysipelas			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (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
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
Acute kidney injury			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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 obstruction			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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
Infections and infestations			
Respiratory tract infection			
subjects affected / exposed	5 / 108 (4.63%)	0 / 36 (0.00%)	5 / 36 (13.89%)
occurrences causally related to treatment / all	2 / 5	0 / 0	2 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1

Catheter related infection			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	4 / 108 (3.70%)	3 / 36 (8.33%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	3 / 4	2 / 3	1 / 1
deaths causally related to treatment / all	2 / 2	2 / 2	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	0 / 36 (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
Rash pustular			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cervix		
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 36 (36.11%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Vascular disorders			
Thromboembolitic event			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Colostomy problems			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fever			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General Weakness			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic shock			

subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Social problem			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Vaginal pain			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic pain			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Neutrophil count decreased			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Platelet count decreased			

subjects affected / exposed	2 / 36 (5.56%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fracture			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Angor			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ascites			

subjects affected / exposed	0 / 36 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstruction				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhage				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 1			
Fistula of small intestine				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Fistula	Additional description: ileo-vaginal-bladder fistula			

subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Erysipelas			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute kidney injury			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Respiratory tract infection			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Catheter related infection			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		

Peritonitis				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	1 / 1			
Sepsis				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	2 / 36 (5.56%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Rash pustular				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 36 (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: 0 %

Non-serious adverse events	Overall trial	Ovarium Cancer	Endometrium
Total subjects affected by non-serious adverse events			
subjects affected / exposed	104 / 108 (96.30%)	36 / 36 (100.00%)	33 / 36 (91.67%)
Vascular disorders			
Thromboembolic event			
subjects affected / exposed	7 / 108 (6.48%)	1 / 36 (2.78%)	4 / 36 (11.11%)
occurrences (all)	7	1	4
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	81 / 108 (75.00%)	31 / 36 (86.11%)	22 / 36 (61.11%)
occurrences (all)	188	73	36
Fever			
subjects affected / exposed	9 / 108 (8.33%)	2 / 36 (5.56%)	2 / 36 (5.56%)
occurrences (all)	11	4	2
Pain			
subjects affected / exposed	25 / 108 (23.15%)	7 / 36 (19.44%)	7 / 36 (19.44%)
occurrences (all)	36	13	9
Oedema			
subjects affected / exposed	3 / 108 (2.78%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	3	1	1
Asthenia			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	2	1	0
Haemorrhage			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration			
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	4	2	0
Infusion related reaction			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	3	0	3
Immune system disorders			

Allergic reaction			
subjects affected / exposed	15 / 108 (13.89%)	8 / 36 (22.22%)	5 / 36 (13.89%)
occurrences (all)	19	8	9
Reproductive system and breast disorders			
Vaginal pain			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	3	0	0
Vaginal infection			
subjects affected / exposed	4 / 108 (3.70%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	4	1	0
Vaginal dryness			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Vaginal atrophy			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	21 / 108 (19.44%)	7 / 36 (19.44%)	5 / 36 (13.89%)
occurrences (all)	46	31	5
Dyspnoea			
subjects affected / exposed	29 / 108 (26.85%)	10 / 36 (27.78%)	7 / 36 (19.44%)
occurrences (all)	38	12	11
Pulmonary embolism			
subjects affected / exposed	4 / 108 (3.70%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	4	1	1
Respiratory failure			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	2	2	0
Laryngeal inflammation			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	2	0	1
Hoarseness			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Psychiatric disorders			

Anxiety			
subjects affected / exposed	8 / 108 (7.41%)	3 / 36 (8.33%)	3 / 36 (8.33%)
occurrences (all)	9	4	3
Agitation			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Alternation of general status			
subjects affected / exposed	2 / 108 (1.85%)	2 / 36 (5.56%)	0 / 36 (0.00%)
occurrences (all)	2	2	0
Confusional state			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Emotional distress			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Insomnia			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	2	0	1
Investigations			
Neutrophil count decreased			
subjects affected / exposed	59 / 108 (54.63%)	16 / 36 (44.44%)	17 / 36 (47.22%)
occurrences (all)	160	37	59
Platelet count decreased			
subjects affected / exposed	64 / 108 (59.26%)	16 / 36 (44.44%)	21 / 36 (58.33%)
occurrences (all)	332	83	114
White blood cell count decreased			
subjects affected / exposed	24 / 108 (22.22%)	9 / 36 (25.00%)	5 / 36 (13.89%)
occurrences (all)	78	32	19
Bilirubin conjugated increased			
subjects affected / exposed	5 / 108 (4.63%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	10	4	2
Alanine aminotransferase increased			

subjects affected / exposed	4 / 108 (3.70%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	14	4	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 108 (2.78%)	2 / 36 (5.56%)	0 / 36 (0.00%)
occurrences (all)	6	3	0
Creatinine urine increased			
subjects affected / exposed	6 / 108 (5.56%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	10	1	2
Ferritine decreased			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Alkaline phosphatase increased			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
GGT increased			
subjects affected / exposed	7 / 108 (6.48%)	1 / 36 (2.78%)	4 / 36 (11.11%)
occurrences (all)	7	1	4
Lymphocyte count decreased			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	3	0	0
Injury, poisoning and procedural complications			
Fracture	Additional description: Fracture toe Fracture cotyle right		
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	3	1	2
Cardiac disorders			
Heart failure			
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	2	1	1
Atrial fibrillation			
subjects affected / exposed	3 / 108 (2.78%)	2 / 36 (5.56%)	0 / 36 (0.00%)
occurrences (all)	3	2	0
Atrial flutter			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Palpitations			

subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Paresthesia			
subjects affected / exposed	7 / 108 (6.48%)	2 / 36 (5.56%)	3 / 36 (8.33%)
occurrences (all)	8	2	4
Peripheral motor neuropathy			
subjects affected / exposed	3 / 108 (2.78%)	2 / 36 (5.56%)	1 / 36 (2.78%)
occurrences (all)	3	2	1
Peripheral sensory neuropathy			
subjects affected / exposed	36 / 108 (33.33%)	10 / 36 (27.78%)	10 / 36 (27.78%)
occurrences (all)	46	11	11
Dysgeusia			
subjects affected / exposed	3 / 108 (2.78%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	4	0	1
Amnesia			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Cerebrovascular accident			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	3	0	1
Dizziness			
subjects affected / exposed	3 / 108 (2.78%)	2 / 36 (5.56%)	0 / 36 (0.00%)
occurrences (all)	3	2	0
Tremor			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Presyncope			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Syncope			
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	3	2	0
Spasms			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0

Restless legs syndrome			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Headache			
subjects affected / exposed	7 / 108 (6.48%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	7	1	1
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	88 / 108 (81.48%)	28 / 36 (77.78%)	26 / 36 (72.22%)
occurrences (all)	392	108	103
Febrile neutropenia			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Hypertension			
subjects affected / exposed	4 / 108 (3.70%)	1 / 36 (2.78%)	2 / 36 (5.56%)
occurrences (all)	6	3	2
Hypotension			
subjects affected / exposed	2 / 108 (1.85%)	2 / 36 (5.56%)	0 / 36 (0.00%)
occurrences (all)	2	2	0
Pleural effusion			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Hearing impaired			
subjects affected / exposed	3 / 108 (2.78%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	3	1	1
Eye disorders			
Conjunctivitis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Dry eye			

subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Watering eyes			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Optic nerve disorder			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	68 / 108 (62.96%)	22 / 36 (61.11%)	21 / 36 (58.33%)
occurrences (all)	117	38	38
Vomiting			
subjects affected / exposed	32 / 108 (29.63%)	13 / 36 (36.11%)	10 / 36 (27.78%)
occurrences (all)	51	20	11
Diarrhoea			
subjects affected / exposed	44 / 108 (40.74%)	17 / 36 (47.22%)	13 / 36 (36.11%)
occurrences (all)	65	30	17
Constipation			
subjects affected / exposed	30 / 108 (27.78%)	7 / 36 (19.44%)	11 / 36 (30.56%)
occurrences (all)	34	9	12
Abdominal pain			
subjects affected / exposed	18 / 108 (16.67%)	4 / 36 (11.11%)	4 / 36 (11.11%)
occurrences (all)	20	5	4
Anorexia nervosa			
subjects affected / exposed	25 / 108 (23.15%)	8 / 36 (22.22%)	8 / 36 (22.22%)
occurrences (all)	29	9	9
hemorrhoides			
subjects affected / exposed	2 / 108 (1.85%)	2 / 36 (5.56%)	0 / 36 (0.00%)
occurrences (all)	2	2	0
Stomach Pain			
subjects affected / exposed	3 / 108 (2.78%)	0 / 36 (0.00%)	2 / 36 (5.56%)
occurrences (all)	3	0	2
Anal fissure			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0

Ascites			
subjects affected / exposed	2 / 108 (1.85%)	2 / 36 (5.56%)	0 / 36 (0.00%)
occurrences (all)	3	3	0
Obstruction			
subjects affected / exposed	7 / 108 (6.48%)	3 / 36 (8.33%)	2 / 36 (5.56%)
occurrences (all)	10	4	3
Colitis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Dyspepsia			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Dysphagia			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Oesophagitis			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Gastritis			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	2	0	1
Stomatitis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Ileus			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Mucositis oral			
subjects affected / exposed	4 / 108 (3.70%)	2 / 36 (5.56%)	1 / 36 (2.78%)
occurrences (all)	6	2	2

Fistula	Additional description: cervico-bladder female genital tract		
subjects affected / exposed	4 / 108 (3.70%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	5	1	0
Gastroenteritis			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	21 / 108 (19.44%)	10 / 36 (27.78%)	5 / 36 (13.89%)
occurrences (all)	25	10	7
Nail loss			
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	2	1	0
Dry skin			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	2	1	1
Rosacea			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Acute Renal insufficiency			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Cystitis			
subjects affected / exposed	4 / 108 (3.70%)	0 / 36 (0.00%)	3 / 36 (8.33%)
occurrences (all)	4	0	3
Urinary incontinence			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Pyelonephritis			

subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Renal failure			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Nocturia			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Pollakiuria			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	2	0	2
Prerenal failure			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Hydronephrosis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			
Muscle discomfort			
subjects affected / exposed	7 / 108 (6.48%)	4 / 36 (11.11%)	2 / 36 (5.56%)
occurrences (all)	7	4	2
Muscle strength abnormal			
subjects affected / exposed	3 / 108 (2.78%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	3	1	1
Myalgia			
subjects affected / exposed	9 / 108 (8.33%)	3 / 36 (8.33%)	1 / 36 (2.78%)
occurrences (all)	10	3	1
Arthralgia			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	2	0	1
Back pain			
subjects affected / exposed	3 / 108 (2.78%)	2 / 36 (5.56%)	1 / 36 (2.78%)
occurrences (all)	4	3	1
Bone pain			

subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	3	0	0
Flank pain			
subjects affected / exposed	3 / 108 (2.78%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	3	0	1
Pain in extremity			
subjects affected / exposed	2 / 108 (1.85%)	2 / 36 (5.56%)	0 / 36 (0.00%)
occurrences (all)	2	2	0
Buttock pain			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Pelvic pain			
subjects affected / exposed	3 / 108 (2.78%)	1 / 36 (2.78%)	1 / 36 (2.78%)
occurrences (all)	3	1	1
Pain footh			
subjects affected / exposed	3 / 108 (2.78%)	2 / 36 (5.56%)	1 / 36 (2.78%)
occurrences (all)	3	2	1
Soft tissue necrosis	Additional description: upper limb		
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	7 / 108 (6.48%)	3 / 36 (8.33%)	1 / 36 (2.78%)
occurrences (all)	10	4	1
Sepsis			
subjects affected / exposed	7 / 108 (6.48%)	3 / 36 (8.33%)	2 / 36 (5.56%)
occurrences (all)	8	3	2
Bladder infection			
subjects affected / exposed	3 / 108 (2.78%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	3	1	0
Respiratory tract infection			
subjects affected / exposed	21 / 108 (19.44%)	8 / 36 (22.22%)	9 / 36 (25.00%)
occurrences (all)	25	9	11
Catheter related infection			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	3	0	3

Wound infection	Additional description: Umbilicale wound infection		
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	2	0	2
Sinusitis			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	4	0	0
Rhinitis			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	2	0	1
Peritonitis			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Lip infection			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Phlebitis			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Bacterial infection	Additional description: MRSA positive		
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	3	0	0
Laryngitis			
subjects affected / exposed	2 / 108 (1.85%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	2	0	1
Inflammatory syndrom			
subjects affected / exposed	1 / 108 (0.93%)	0 / 36 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	21 / 108 (19.44%)	8 / 36 (22.22%)	4 / 36 (11.11%)
occurrences (all)	53	34	5
Hypomagnesaemia			

subjects affected / exposed	15 / 108 (13.89%)	6 / 36 (16.67%)	4 / 36 (11.11%)
occurrences (all)	23	7	7
Hypocalcaemia			
subjects affected / exposed	2 / 108 (1.85%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	5	4	0
Hyponatraemia			
subjects affected / exposed	1 / 108 (0.93%)	1 / 36 (2.78%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Hyperglycaemia			
subjects affected / exposed	3 / 108 (2.78%)	0 / 36 (0.00%)	1 / 36 (2.78%)
occurrences (all)	4	0	1

Non-serious adverse events	Cervix		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 36 (97.22%)		
Vascular disorders			
Thromboembolic event			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	2		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	28 / 36 (77.78%)		
occurrences (all)	79		
Fever			
subjects affected / exposed	5 / 36 (13.89%)		
occurrences (all)	5		
Pain			
subjects affected / exposed	11 / 36 (30.56%)		
occurrences (all)	14		
Oedema			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Asthenia			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Malaise			

subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Haemorrhage			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
General physical health deterioration			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	2		
Infusion related reaction			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Allergic reaction			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	2		
Reproductive system and breast disorders			
Vaginal pain			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	3		
Vaginal infection			
subjects affected / exposed	3 / 36 (8.33%)		
occurrences (all)	3		
Vaginal dryness			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Vaginal atrophy			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	9 / 36 (25.00%)		
occurrences (all)	10		
Dyspnoea			
subjects affected / exposed	12 / 36 (33.33%)		
occurrences (all)	15		
Pulmonary embolism			

subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	2		
Respiratory failure			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Laryngeal inflammation			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Hoarseness			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	2		
Agitation			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Alternation of general status			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Emotional distress			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Investigations			
Neutrophil count decreased			

subjects affected / exposed	26 / 36 (72.22%)		
occurrences (all)	64		
Platelet count decreased			
subjects affected / exposed	27 / 36 (75.00%)		
occurrences (all)	135		
White blood cell count decreased			
subjects affected / exposed	10 / 36 (27.78%)		
occurrences (all)	27		
Bilirubin conjugated increased			
subjects affected / exposed	3 / 36 (8.33%)		
occurrences (all)	4		
Alanine aminotransferase increased			
subjects affected / exposed	3 / 36 (8.33%)		
occurrences (all)	10		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	3		
Creatinine urine increased			
subjects affected / exposed	4 / 36 (11.11%)		
occurrences (all)	7		
Ferritine decreased			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Alkaline phosphatase increased			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
GGT increased			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	2		
Lymphocyte count decreased			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			

Fracture	Additional description: Fracture toe Fracture cotyle right		
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Heart failure			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Atrial fibrillation			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Atrial flutter			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Paresthesia			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	2		
Peripheral motor neuropathy			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	16 / 36 (44.44%)		
occurrences (all)	23		
Dysgeusia			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	3		
Amnesia			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Cerebrovascular accident			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Dizziness			

subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Tremor			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	2		
Syncope			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Spasms			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Restless legs syndrome			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	5 / 36 (13.89%)		
occurrences (all)	5		
Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	34 / 36 (94.44%)		
occurrences (all)	181		
Febrile neutropenia			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Hypotension			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		

Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Tinnitus			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Hearing impaired			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	2		
Watering eyes			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Optic nerve disorder			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	25 / 36 (69.44%)		
occurrences (all)	41		
Vomiting			
subjects affected / exposed	9 / 36 (25.00%)		
occurrences (all)	20		
Diarrhoea			
subjects affected / exposed	14 / 36 (38.89%)		
occurrences (all)	18		
Constipation			
subjects affected / exposed	12 / 36 (33.33%)		
occurrences (all)	13		
Abdominal pain			

subjects affected / exposed	10 / 36 (27.78%)			
occurrences (all)	11			
Anorexia nervosa				
subjects affected / exposed	9 / 36 (25.00%)			
occurrences (all)	11			
hemorrhoides				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Stomach Pain				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences (all)	1			
Anal fissure				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Ascites				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Obstruction				
subjects affected / exposed	2 / 36 (5.56%)			
occurrences (all)	3			
Colitis				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Epistaxis				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences (all)	1			
Oesophagitis				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Toothache				

subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Ileus			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Mucositis oral			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	2		
Fistula	Additional description: cervico-bladder female genital tract		
subjects affected / exposed	3 / 36 (8.33%)		
occurrences (all)	4		
Gastroenteritis			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	6 / 36 (16.67%)		
occurrences (all)	8		
Nail loss			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Dry skin			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Rosacea			

subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Acute Renal insufficiency			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Urinary incontinence			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Pyelonephritis			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Renal failure			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Nocturia			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Prerenal failure			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Hydronephrosis			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			

Muscle discomfort				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences (all)	1			
Muscle strength abnormal				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences (all)	1			
Myalgia				
subjects affected / exposed	5 / 36 (13.89%)			
occurrences (all)	6			
Arthralgia				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences (all)	1			
Back pain				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Bone pain				
subjects affected / exposed	2 / 36 (5.56%)			
occurrences (all)	3			
Flank pain				
subjects affected / exposed	2 / 36 (5.56%)			
occurrences (all)	2			
Pain in extremity				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Buttock pain				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Pelvic pain				
subjects affected / exposed	1 / 36 (2.78%)			
occurrences (all)	1			
Pain footh				
subjects affected / exposed	0 / 36 (0.00%)			
occurrences (all)	0			
Soft tissue necrosis	Additional description: upper limb			
subjects affected / exposed	1 / 36 (2.78%)			
occurrences (all)	1			

Infections and infestations			
Urinary tract infection			
subjects affected / exposed	3 / 36 (8.33%)		
occurrences (all)	5		
Sepsis			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	3		
Bladder infection			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	2		
Respiratory tract infection			
subjects affected / exposed	4 / 36 (11.11%)		
occurrences (all)	5		
Catheter related infection			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Wound infection	Additional description: Umbilicale wound infection		
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	4		
Rhinitis			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Peritonitis			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Lip infection			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Phlebitis			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Bacterial infection	Additional description: MRSA positive		

subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Infection			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	3		
Laryngitis			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Inflammatory syndrom			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	9 / 36 (25.00%)		
occurrences (all)	14		
Hypomagnesaemia			
subjects affected / exposed	5 / 36 (13.89%)		
occurrences (all)	9		
Hypocalcaemia			
subjects affected / exposed	1 / 36 (2.78%)		
occurrences (all)	1		
Hyponatraemia			
subjects affected / exposed	0 / 36 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			
subjects affected / exposed	2 / 36 (5.56%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26049123