Clinical trial results:
A Phase II, Randomised, Factorial, Double-blind Study to Investigate the Management of AZD2171 (RECENTIN™)-induced Hypertension and Efficacy of AZD2171 at Doses of 30 mg and 45 mg in Patients with Advanced Solid Tumours

Summary

EudraCT number	2005-003442-33
Trial protocol	GB DE
Global end of trial date	26 April 2011

Results information

Result version number	v1 (current)
This version publication date	13 December 2021
First version publication date	13 December 2021

Trial information

Trial identification

Sponsor protocol code	D8480C00038

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AstraZeneca
Sponsor organisation address	1 Francis Crick Avenue, Cambridge Biomedical Campus, United Kingdom, CB2 0AA
Public contact	Tsveta Milenkova, AstraZeneca, ClinicalTrialTransparency@astrazeneca.com
Scientific contact	Gerard Lynch, AstraZeneca, aztrial_results_posting@astrazeneca.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	26 April 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 January 2007
Global end of trial reached?	Yes
Global end of trial date	26 April 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Identify a treatment strategy, consisting of a dose of AZD2171 and a hypertension management strategy (pre-defined management of emergent hypertension ± prophylaxis) that was well tolerated without significant drug withdrawal or dose reduction during the first 12 weeks of therapy with AZD2171.

Protection of trial subjects:

de-escalation dose recommended: CTCAE grade 3 or higher toxicities of duration >3 days that were considered to be related to study treatment and were not responding to maximal supportive care within 48 hours, at the discretion of the investigator.

Excluding hypertension, toxicity attributable to AZD2171 management plan: if symptoms did not resolve to CTCAE grade 2 or below with maximum supportive care, the next dose level of AZD2171 below that being dosed was to be instituted (30mg became 20mg, 45mg became 30mg etc). Investigators could choose to reduce the dose of AZD2171, hold dosing for up to 14 days or withdraw the patient from the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 November 2005
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	Germany: 38
Country: Number of subjects enrolled	Netherlands: 68
Country: Number of subjects enrolled	United Kingdom: 27
Worldwide total number of subjects	133
EEA total number of subjects	133

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	103
From 65 to 84 years	30
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients enrolled = 133; ITT analysis set = 126

AZD2171 30mg (Antihypertensive prophylaxis) = 30
AZD2171 30mg (no-Antihypertensive prophylaxis) = 32
AZD2171 45mg (Antihypertensive prophylaxis) = 30
AZD2171 45mg (no-Antihypertensive prophylaxis) = 34

Pre-assignment

Screening details:

Not randomised = 7; eligibility criteria not fulfilled = 6; screening failure = 1

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	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Blinding implementation details:

randomisation was done using software and RNG. No personnel were aware of the randomisation process untill all data was collected

Arms

Are arms mutually exclusive?	Yes
Arm title	AZD2171 30 mg Anti HT

Arm description:

AZD2171 30 mg AntiHT prophylaxis

Arm type	Experimental
Investigational medicinal product name	RECENTIN™, cediranib (Anti HT - amlodipine 2.5 mg/day or nifedipine 30 mg/day or felodipine 2.5 mg/day)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

AZD2171 was administered orally, once daily as a 1 x 30 mg tablet plus 1 x 15 mg placebo tablet (ie, total AZD2171 dose of 30 mg). Patients could continue indefinitely, provided they do not meet the exclusion criteria, were free from intolerable toxicity, and were receiving some benefit (in the investigator's opinion)

Arm title	AZD2171 30 mg No Anti HT

Arm description:

AZD2171 30 mg No AntiHT prophylaxis

Arm type	Experimental
Investigational medicinal product name	RECENTIN™, cediranib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

AZD2171 was administered orally, once daily as a 1 x 30 mg tablet plus 1 x 15 mg placebo tablet (ie, total AZD2171 dose of 30 mg). Patients could continue indefinitely, provided they do not meet the exclusion criteria, were free from intolerable toxicity, and were receiving some benefit (in the

investigator's opinion)

Arm title	AZD2171 45 mg Anti HT
Arm description: AZD2171 45 mg AntiHT prophylaxis	
Arm type	Experimental
Investigational medicinal product name	RECENTIN™, cediranib (Anti HT - amlodipine 2.5 mg/day or nifedipine 30 mg/day or felodipine 2.5 mg/day)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: administered orally once daily as 1 x 30mg tablet + 1 x 15mg tablet. Patients could continue indefinitely, provided they do not meet the exclusion criteria, were free from intolerable toxicity, and were receiving some benefit (in the investigator's opinion)	

Arm title	AZD2171 45 mg No Anti HT
Arm description: AZD2171 45 mg No AntiHT prophylaxis	
Arm type	Experimental
Investigational medicinal product name	RECENTIN™, cediranib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: administered orally once daily as 1 x 30mg tablet + 1 x 15mg tablet. Patients could continue indefinitely, provided they do not meet the exclusion criteria, were free from intolerable toxicity, and were receiving some benefit (in the investigator's opinion)	

Number of subjects in period 1[1]	AZD2171 30 mg Anti HT	AZD2171 30 mg No Anti HT	AZD2171 45 mg Anti HT
Started	30	32	30
Completed	13	21	16
Not completed	17	11	14
Consent withdrawn by subject	-	1	2
Adverse event, non-fatal	2	3	6
Not specified	2	2	-
Cond. under inv. worsened	9	5	3
Development study specific disc. crit.	1	-	1
Not treated	3	-	2

Number of subjects in period 1	AZD2171 45 mg No Anti HT

[1]	
Started	34
Completed	19
Not completed	15
Consent withdrawn by subject	2
Adverse event, non-fatal	4
Not specified	3
Cond. under inv. worsened	4
Development study specific disc. crit.	-
Not treated	2

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Results are provided for the 126 randomized subjects, following the definition of ITT used in the study. 133 patients were enrolled, of which 7 were not randomized [(Eligibility criteria not fulfilled = 6) (Screening failure = 1)]

Baseline characteristics

Reporting groups	
Reporting group title	AZD2171 30 mg Anti HT
Reporting group description: AZD2171 30 mg AntiHT prophylaxis	
Reporting group title	AZD2171 30 mg No Anti HT
Reporting group description: AZD2171 30 mg No AntiHT prophylaxis	
Reporting group title	AZD2171 45 mg Anti HT
Reporting group description: AZD2171 45 mg AntiHT prophylaxis	
Reporting group title	AZD2171 45 mg No Anti HT
Reporting group description: AZD2171 45 mg No AntiHT prophylaxis	

Reporting group values	AZD2171 30 mg Anti HT	AZD2171 30 mg No Anti HT	AZD2171 45 mg Anti HT
Number of subjects	30	32	30
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	22	26	21
From 65-84 years	8	6	9
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	58.1	52.7	56.4
standard deviation	± 9.3	± 12.9	± 11.0
Gender, Male/Female Units: Subjects			
Female	12	16	13
Male	18	16	17
Race Units: Subjects			
Caucasian	28	32	29
Black	0	0	1
Oriental	1	0	0
Other	1	0	0
Number of prior regimens Units: Subjects			
Zero	4	9	8
One	7	7	2

Two	7	3	7
Three	1	8	4
Four	8	3	3
Five	2	1	4
More than six	1	1	2

Reporting group values	AZD2171 45 mg No Anti HT	Total	
Number of subjects	34	126	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	28	97	
From 65-84 years	6	29	
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	53.5		
standard deviation	± 11.7	-	
Gender, Male/Female Units: Subjects			
Female	25	66	
Male	9	60	
Race Units: Subjects			
Caucasian	33	122	
Black	0	1	
Oriental	0	1	
Other	1	2	
Number of prior regimens Units: Subjects			
Zero	6	27	
One	6	22	
Two	4	21	
Three	5	18	
Four	4	18	
Five	6	13	
More than six	3	7	

End points

End points reporting groups

Reporting group title	AZD2171 30 mg Anti HT
Reporting group description: AZD2171 30 mg AntiHT prophylaxis	
Reporting group title	AZD2171 30 mg No Anti HT
Reporting group description: AZD2171 30 mg No AntiHT prophylaxis	
Reporting group title	AZD2171 45 mg Anti HT
Reporting group description: AZD2171 45 mg AntiHT prophylaxis	
Reporting group title	AZD2171 45 mg No Anti HT
Reporting group description: AZD2171 45 mg No AntiHT prophylaxis	

Primary: Proportion of patients requiring temporary (>1 day) or permanent withdrawal of AZD2171 prior to progression and within 12 weeks of first dose of AZD2171

End point title	Proportion of patients requiring temporary (>1 day) or permanent withdrawal of AZD2171 prior to progression and within 12 weeks of first dose of AZD2171[1]
End point description:	
End point type	Primary
End point timeframe: 12 week treatment 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 formal statistical analyses were specified or conducted for this endpoint, there observed number of patients was summarised separately by treatment arm.

End point values	AZD2171 30 mg Anti HT	AZD2171 30 mg No Anti HT	AZD2171 45 mg Anti HT	AZD2171 45 mg No Anti HT
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	32	30	34
Units: Participants	12	19	20	24

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of planned dose received during first 12 weeks of therapy with AZD2171

End point title	Proportion of planned dose received during first 12 weeks of therapy with AZD2171[2]

End point description:

Total actual dose received during the first 12 weeks prior to progression divided by the planned dose (planned dose: initial allocated dose multiplied by the number of days on study during the first 12 weeks prior to progression)

End point type	Primary

End point timeframe:

12 week treatment period

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 formal statistical analyses were specified or conducted for this endpoint, there observed number of patients was summarised separately by treatment arm.

End point values	AZD2171 30 mg Anti HT	AZD2171 30 mg No Anti HT	AZD2171 45 mg Anti HT	AZD2171 45 mg No Anti HT
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	32	30	34
Units: Poportion of Planned Dose				
median (confidence interval 90%)	0.89 (0.62 to 1.00)	0.88 (0.76 to 0.98)	0.74 (0.58 to .91)	0.79 (0.64 to 0.87)

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of patients requiring temporary (>1 day) or permanent withdrawal of AZD2171 prior to progression and within 6 weeks of first dose of AZD2171

End point title	Proportion of patients requiring temporary (>1 day) or permanent withdrawal of AZD2171 prior to progression and within 6 weeks of first dose of AZD2171

End point description:

End point type	Secondary

End point timeframe:

First 6 weeks of 12 week treatment period

End point values	AZD2171 30 mg Anti HT	AZD2171 30 mg No Anti HT	AZD2171 45 mg Anti HT	AZD2171 45 mg No Anti HT
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	32	30	34
Units: Participants	9	9	16	19

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate

End point title	Objective response rate

End point description:

Number of patients with complete or partial response (CR/PR), based on RECIST

End point type	Secondary

End point timeframe:

12 week treatment period

End point values	AZD2171 30 mg Anti HT	AZD2171 30 mg No Anti HT	AZD2171 45 mg Anti HT	AZD2171 45 mg No Anti HT
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	32	30	34
Units: Participants	1	3	2	3

Statistical analyses

No statistical analyses for this end point

Secondary: Best percentage change in tumour size

End point title	Best percentage change in tumour size

End point description:

Maximum percentage reduction or minimum percentage increase in tumour size where size is the sum of the longest diameters of the target lesions. Based on the baseline scaled ratio: ratio of the post-randomisation visit tumour size divided by the baseline tumour size.

End point type	Secondary

End point timeframe:

Randomisation until end of treatment period

End point values	AZD2171 30 mg Anti HT	AZD2171 30 mg No Anti HT	AZD2171 45 mg Anti HT	AZD2171 45 mg No Anti HT
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	29	21	27
Units: percentage of tumor size				
geometric mean (confidence interval 90%)	-1.12 (-8.96 to 7.38)	-10.81 (-23.99 to 4.65)	-11.78 (-22.53 to 0.46)	-13.13 (-20.39 to -5.21)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From first dose of study drug until last study visit	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	17
Reporting groups	
Reporting group title	AZD2171 30mg AntiHT Prophylaxis
Reporting group description: -	
Reporting group title	AZD2171 30mg No AntiHT Prophylaxis
Reporting group description: AZD2171 30mg No AntiHT Prophylaxis	
Reporting group title	AZD2171 45mg AntiHT Prophylaxis
Reporting group description: -	
Reporting group title	AZD2171 45mg No AntiHT Prophylaxis
Reporting group description: AZD2171 45mg No AntiHT Prophylaxis	

Serious adverse events	AZD2171 30mg AntiHT Prophylaxis	AZD2171 30mg No AntiHT Prophylaxis	AZD2171 45mg AntiHT Prophylaxis
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 28 (39.29%)	20 / 31 (64.52%)	14 / 26 (53.85%)
number of deaths (all causes)	10	10	10
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
HYPERTENSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 28 (14.29%)	3 / 31 (9.68%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	5 / 5	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			

alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
VENOUS THROMBOSIS LIMB			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
General disorders and administration site conditions			
EUTHANASIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
FATIGUE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	1 / 31 (3.23%)	2 / 26 (7.69%)
occurrences causally related to treatment / all	1 / 2	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GENERAL PHYSICAL HEALTH DETERIORATION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
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 dictionary used: MedDRA 17			

subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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 dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	2 / 31 (6.45%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
DYSPNOEA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
PNEUMOTHORAX			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STRIDOR			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
CONFUSIONAL STATE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
Investigations			
BLOOD BILIRUBIN INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC ENZYME INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
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 ISCHAEMIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALPITATIONS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUS TACHYCARDIA			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
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			
CEREBRAL ISCHAEMIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGE INTRACRANIAL			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
HEMIPARESIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOMNOLENCE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
VERTIGO			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
Eye disorders			
RETINAL VEIN THROMBOSIS			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	2 / 31 (6.45%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN LOWER			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN UPPER			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	0 / 31 (0.00%)	0 / 26 (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
ASCITES			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	0 / 31 (0.00%)	0 / 26 (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
CONSTIPATION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
DIARRHOEA			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 28 (7.14%)	3 / 31 (9.68%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	2 / 2	3 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEUS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
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 INTESTINAL HAEMORRHAGE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
PANCREATITIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	0 / 31 (0.00%)	0 / 26 (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

SUBILEUS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	2 / 31 (6.45%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 1	0 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLECYSTITIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLESTASIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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			
LEUKOPLAKIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
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			
HAEMATURIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROTEINURIA			

alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
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 IMPAIRMENT			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
URETHRAL PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
Musculoskeletal and connective tissue disorders			
BACK PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	0 / 31 (0.00%)	0 / 26 (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
JOINT SWELLING			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYALGIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN EXTREMITY			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
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			
ERYSIPELAS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED SKIN ULCER			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARYNGITIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
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 TRACT INFECTION			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
UROSEPSIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
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			
ANOREXIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	3 / 26 (11.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERCALCAEMIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (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
HYPONATRAEMIA			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	AZD2171 45mg No AntiHT Prophylaxis		
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 34 (70.59%)		
number of deaths (all causes)	14		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
HYPERTENSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 34 (14.71%)		
occurrences causally related to treatment / all	5 / 5		
deaths causally related to treatment / all	0 / 0		
HYPOTENSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
VENOUS THROMBOSIS LIMB			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
EUTHANASIA			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FATIGUE				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
GENERAL PHYSICAL HEALTH DETERIORATION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
MALAISE				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
NON-CARDIAC CHEST PAIN				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PYREXIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
DYSPNOEA				
alternative dictionary used: MedDRA 17				

subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
HYPOXIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
PLEURAL EFFUSION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMOTHORAX				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
STRIDOR				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
CONFUSIONAL STATE				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
BLOOD BILIRUBIN INCREASED				
alternative dictionary used: MedDRA 17				

subjects affected / exposed	2 / 34 (5.88%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
HEPATIC ENZYME INCREASED				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
MYOCARDIAL ISCHAEMIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PALPITATIONS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
SINUS TACHYCARDIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
CEREBRAL ISCHAEMIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
HAEMORRHAGE INTRACRANIAL				
alternative dictionary used: MedDRA 17				

subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
HEMIPARESIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
SOMNOLENCE				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
VERTIGO				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
RETINAL VEIN THROMBOSIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
ABDOMINAL PAIN				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
ABDOMINAL PAIN LOWER				
alternative dictionary used: MedDRA 17				

subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ABDOMINAL PAIN UPPER				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
ASCITES				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
CONSTIPATION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
DIARRHOEA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
DYSPHAGIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
ILEUS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

INTESTINAL OBSTRUCTION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
LARGE INTESTINAL HAEMORRHAGE				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
NAUSEA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PANCREATITIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SUBILEUS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
VOMITING				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	3 / 34 (8.82%)			
occurrences causally related to treatment / all	3 / 4			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
CHOLECYSTITIS				
alternative dictionary used: MedDRA 17				

subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CHOLESTASIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
LEUKOPLAKIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
HAEMATURIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PROTEINURIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
RENAL IMPAIRMENT				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
URETHRAL PAIN				
alternative dictionary used: MedDRA 17				

subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
BACK PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
JOINT SWELLING			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
MYALGIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
PAIN IN EXTREMITY			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
ERYSIPELAS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
INFECTED SKIN ULCER			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
LARYNGITIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
LUNG INFECTION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PYELONEPHRITIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
RESPIRATORY TRACT INFECTION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
URINARY TRACT INFECTION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
UROSEPSIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Metabolism and nutrition disorders			
ANOREXIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
DEHYDRATION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
HYPERCALCAEMIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HYPONATRAEMIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	AZD2171 30mg AntiHT Prophylaxis	AZD2171 30mg No AntiHT Prophylaxis	AZD2171 45mg AntiHT Prophylaxis
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 28 (96.43%)	31 / 31 (100.00%)	26 / 26 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 28 (17.86%)	2 / 31 (6.45%)	2 / 26 (7.69%)
occurrences (all)	6	2	2
Vascular disorders			

FLUSHING			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
HYPERTENSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	15 / 28 (53.57%)	21 / 31 (67.74%)	19 / 26 (73.08%)
occurrences (all)	16	26	23
HYPOTENSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	2 / 31 (6.45%)	1 / 26 (3.85%)
occurrences (all)	2	2	1
General disorders and administration site conditions			
ASTHENIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences (all)	1	1	1
CHEST DISCOMFORT			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
CHILLS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences (all)	4	1	1
FACE OEDEMA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
FATIGUE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	19 / 28 (67.86%)	20 / 31 (64.52%)	20 / 26 (76.92%)
occurrences (all)	23	28	25
INFLUENZA LIKE ILLNESS			
alternative dictionary used:			

MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences (all)	4	1	0
MUCOSAL INFLAMMATION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	4 / 31 (12.90%)	3 / 26 (11.54%)
occurrences (all)	1	4	4
NON-CARDIAC CHEST PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	2 / 26 (7.69%)
occurrences (all)	0	1	3
OEDEMA PERIPHERAL			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	3 / 31 (9.68%)	2 / 26 (7.69%)
occurrences (all)	2	5	2
PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
PYREXIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	5 / 31 (16.13%)	2 / 26 (7.69%)
occurrences (all)	3	6	3
TEMPERATURE INTOLERANCE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	1 / 26 (3.85%)
occurrences (all)	0	2	1
Respiratory, thoracic and mediastinal disorders			
COUGH			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 28 (14.29%)	7 / 31 (22.58%)	6 / 26 (23.08%)
occurrences (all)	5	9	8
DYSPHONIA			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	15 / 28 (53.57%)	16 / 31 (51.61%)	19 / 26 (73.08%)
occurrences (all)	16	17	24
DYSPNOEA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	5 / 31 (16.13%)	3 / 26 (11.54%)
occurrences (all)	4	5	6
DYSPNOEA EXERTIONAL			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	3 / 31 (9.68%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
EPISTAXIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	3 / 31 (9.68%)	2 / 26 (7.69%)
occurrences (all)	0	3	2
NASAL CONGESTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
PHARYNGOLARYNGEAL PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
PLEURAL EFFUSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
Psychiatric disorders			
CONFUSIONAL STATE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
DEPRESSION			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 28 (0.00%)	3 / 31 (9.68%)	0 / 26 (0.00%)
occurrences (all)	0	3	0
INSOMNIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	5 / 31 (16.13%)	2 / 26 (7.69%)
occurrences (all)	1	6	3
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	2 / 31 (6.45%)	0 / 26 (0.00%)
occurrences (all)	2	2	0
ASPARTATE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
BLOOD ALBUMIN DECREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
BLOOD ALKALINE PHOSPHATASE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
BLOOD BILIRUBIN INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
BLOOD CREATININE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
BLOOD THYROID STIMULATING HORMONE INCREASED			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 28 (10.71%)	2 / 31 (6.45%)	2 / 26 (7.69%)
occurrences (all)	5	2	3
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
TRANSAMINASES INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences (all)	2	1	2
WEIGHT DECREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 28 (17.86%)	8 / 31 (25.81%)	8 / 26 (30.77%)
occurrences (all)	5	10	8
Cardiac disorders			
SINUS BRADYCARDIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
SINUS TACHYCARDIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
Nervous system disorders			
DIZZINESS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	3 / 31 (9.68%)	6 / 26 (23.08%)
occurrences (all)	2	4	8
DYSGEUSIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
HEADACHE			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 28 (7.14%)	7 / 31 (22.58%)	9 / 26 (34.62%)
occurrences (all)	3	10	10
MEMORY IMPAIRMENT			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
NEURALGIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
NEUROPATHY PERIPHERAL			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences (all)	2	0	1
PERIPHERAL SENSORY NEUROPATHY			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 28 (14.29%)	3 / 31 (9.68%)	1 / 26 (3.85%)
occurrences (all)	4	4	1
Blood and lymphatic system disorders			
ANAEMIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	5 / 31 (16.13%)	0 / 26 (0.00%)
occurrences (all)	0	6	0
NEUTROPENIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
THROMBOCYTOPENIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
EAR DISCOMFORT			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 28 (7.14%)	2 / 31 (6.45%)	1 / 26 (3.85%)
occurrences (all)	2	2	1
TINNITUS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Eye disorders			
VISION BLURRED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	3 / 31 (9.68%)	0 / 26 (0.00%)
occurrences (all)	1	3	0
VISUAL ACUITY REDUCED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	3 / 26 (11.54%)
occurrences (all)	0	1	3
Gastrointestinal disorders			
ABDOMINAL PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 28 (14.29%)	3 / 31 (9.68%)	6 / 26 (23.08%)
occurrences (all)	5	3	8
ABDOMINAL PAIN LOWER			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	1 / 26 (3.85%)
occurrences (all)	0	2	1
ABDOMINAL PAIN UPPER			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	4 / 26 (15.38%)
occurrences (all)	0	2	4
ASCITES			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences (all)	5	1	1
CONSTIPATION			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	6 / 28 (21.43%)	9 / 31 (29.03%)	5 / 26 (19.23%)
occurrences (all)	8	14	6
DIARRHOEA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	24 / 28 (85.71%)	23 / 31 (74.19%)	20 / 26 (76.92%)
occurrences (all)	43	50	40
DRY MOUTH			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	3 / 31 (9.68%)	6 / 26 (23.08%)
occurrences (all)	3	3	6
DYSPEPSIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 28 (14.29%)	3 / 31 (9.68%)	3 / 26 (11.54%)
occurrences (all)	4	3	3
DYSPHAGIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	2 / 31 (6.45%)	4 / 26 (15.38%)
occurrences (all)	3	3	6
FLATULENCE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	0 / 31 (0.00%)	2 / 26 (7.69%)
occurrences (all)	3	0	2
HAEMORRHOIDS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	1 / 26 (3.85%)
occurrences (all)	0	2	2
MOUTH ULCERATION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
NAUSEA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	9 / 28 (32.14%)	17 / 31 (54.84%)	8 / 26 (30.77%)
occurrences (all)	13	21	8

RECTAL HAEMORRHAGE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
STOMATITIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 28 (25.00%)	10 / 31 (32.26%)	13 / 26 (50.00%)
occurrences (all)	9	12	23
VOMITING			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 28 (28.57%)	9 / 31 (29.03%)	5 / 26 (19.23%)
occurrences (all)	12	15	8
Skin and subcutaneous tissue disorders			
ALOPECIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	5 / 26 (19.23%)
occurrences (all)	0	0	5
DRY SKIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 28 (17.86%)	5 / 31 (16.13%)	6 / 26 (23.08%)
occurrences (all)	6	6	6
ERYTHEMA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
HYPERHIDROSIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	2 / 26 (7.69%)
occurrences (all)	0	2	2
HYPERKERATOSIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
NAIL DISORDER			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 28 (3.57%)	3 / 31 (9.68%)	3 / 26 (11.54%)
occurrences (all)	2	4	4
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 28 (17.86%)	5 / 31 (16.13%)	10 / 26 (38.46%)
occurrences (all)	5	7	15
PIGMENTATION DISORDER			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
PRURITUS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	1 / 31 (3.23%)	4 / 26 (15.38%)
occurrences (all)	3	1	4
RASH			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	6 / 26 (23.08%)
occurrences (all)	0	1	7
RASH GENERALISED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Renal and urinary disorders			
DYSURIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences (all)	1	2	1
POLLAKIURIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
PROTEINURIA			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 28 (0.00%)	4 / 31 (12.90%)	2 / 26 (7.69%)
occurrences (all)	0	4	2
Endocrine disorders			
HYPOTHYROIDISM			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	4 / 31 (12.90%)	5 / 26 (19.23%)
occurrences (all)	2	5	5
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	6 / 31 (19.35%)	6 / 26 (23.08%)
occurrences (all)	3	6	7
BACK PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 28 (14.29%)	5 / 31 (16.13%)	4 / 26 (15.38%)
occurrences (all)	5	5	4
JOINT SWELLING			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
MUSCLE SPASMS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
MUSCULAR WEAKNESS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 28 (10.71%)	1 / 31 (3.23%)	2 / 26 (7.69%)
occurrences (all)	3	1	4
MUSCULOSKELETAL CHEST PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
MUSCULOSKELETAL PAIN			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 28 (7.14%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
MYALGIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 28 (17.86%)	2 / 31 (6.45%)	6 / 26 (23.08%)
occurrences (all)	6	2	10
NECK PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	1 / 26 (3.85%)
occurrences (all)	0	2	1
PAIN IN EXTREMITY			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	5 / 31 (16.13%)	0 / 26 (0.00%)
occurrences (all)	2	6	0
Infections and infestations			
CYSTITIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	1 / 31 (3.23%)	1 / 26 (3.85%)
occurrences (all)	1	1	1
GASTROINTESTINAL INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
HERPES ZOSTER			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	2 / 31 (6.45%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
LOWER RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 28 (10.71%)	7 / 31 (22.58%)	4 / 26 (15.38%)
occurrences (all)	4	9	5
ORAL CANDIDIASIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 28 (7.14%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
RASH PUSTULAR			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
RHINITIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	2 / 31 (6.45%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
UPPER RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	0 / 31 (0.00%)	5 / 26 (19.23%)
occurrences (all)	1	0	6
URINARY TRACT INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	3 / 31 (9.68%)	3 / 26 (11.54%)
occurrences (all)	1	3	3
VIRAL INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	0 / 31 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
ANOREXIA			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	8 / 28 (28.57%)	14 / 31 (45.16%)	13 / 26 (50.00%)
occurrences (all)	10	18	18
DECREASED APPETITE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 28 (3.57%)	1 / 31 (3.23%)	0 / 26 (0.00%)
occurrences (all)	1	2	0
HYPERCALCAEMIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 28 (0.00%)	0 / 31 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1

Non-serious adverse events	AZD2171 45mg No AntiHT Prophylaxis		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 34 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
CANCER PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 34 (14.71%)		
occurrences (all)	6		
Vascular disorders			
FLUSHING			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
HYPERTENSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	25 / 34 (73.53%)		
occurrences (all)	30		
HYPOTENSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
General disorders and administration site conditions			
ASTHENIA			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	2			
CHEST DISCOMFORT				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences (all)	0			
CHILLS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences (all)	1			
FACE OEDEMA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences (all)	0			
FATIGUE				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	23 / 34 (67.65%)			
occurrences (all)	29			
INFLUENZA LIKE ILLNESS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	4 / 34 (11.76%)			
occurrences (all)	4			
MUCOSAL INFLAMMATION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	3 / 34 (8.82%)			
occurrences (all)	4			
NON-CARDIAC CHEST PAIN				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	3 / 34 (8.82%)			
occurrences (all)	3			
OEDEMA PERIPHERAL				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	3 / 34 (8.82%)			
occurrences (all)	3			

PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
PYREXIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	3		
TEMPERATURE INTOLERANCE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
COUGH			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	9 / 34 (26.47%)		
occurrences (all)	13		
DYSPHONIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	18 / 34 (52.94%)		
occurrences (all)	23		
DYSPNOEA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 34 (17.65%)		
occurrences (all)	7		
DYSPNOEA EXERTIONAL			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences (all)	0		
EPISTAXIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
NASAL CONGESTION			
alternative dictionary used:			

MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
PHARYNGOLARYNGEAL PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	3		
PLEURAL EFFUSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
Psychiatric disorders			
CONFUSIONAL STATE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
DEPRESSION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 34 (11.76%)		
occurrences (all)	4		
INSOMNIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences (all)	0		
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 34 (14.71%)		
occurrences (all)	5		
ASPARTATE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	3		
BLOOD ALBUMIN DECREASED			

alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
BLOOD ALKALINE PHOSPHATASE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	3		
BLOOD BILIRUBIN INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
BLOOD CREATININE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
BLOOD THYROID STIMULATING HORMONE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 34 (14.71%)		
occurrences (all)	8		
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 34 (11.76%)		
occurrences (all)	4		
TRANSAMINASES INCREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
WEIGHT DECREASED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 34 (14.71%)		
occurrences (all)	5		
Cardiac disorders			

SINUS BRADYCARDIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
SINUS TACHYCARDIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
DIZZINESS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 34 (17.65%)		
occurrences (all)	7		
DYSGEUSIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
HEADACHE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 34 (20.59%)		
occurrences (all)	8		
MEMORY IMPAIRMENT			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
NEURALGIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
NEUROPATHY PERIPHERAL			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences (all)	0		
PERIPHERAL SENSORY NEUROPATHY			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	3		
Blood and lymphatic system disorders			
ANAEMIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
NEUTROPENIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
THROMBOCYTOPENIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 34 (14.71%)		
occurrences (all)	8		
Ear and labyrinth disorders			
EAR DISCOMFORT			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
TINNITUS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
Eye disorders			
VISION BLURRED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences (all)	0		
VISUAL ACUITY REDUCED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 34 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			

ABDOMINAL PAIN				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	8 / 34 (23.53%)			
occurrences (all)	8			
ABDOMINAL PAIN LOWER				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences (all)	0			
ABDOMINAL PAIN UPPER				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	4 / 34 (11.76%)			
occurrences (all)	5			
ASCITES				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	2			
CONSTIPATION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	9 / 34 (26.47%)			
occurrences (all)	10			
DIARRHOEA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	25 / 34 (73.53%)			
occurrences (all)	51			
DRY MOUTH				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	5 / 34 (14.71%)			
occurrences (all)	5			
DYSPEPSIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	3 / 34 (8.82%)			
occurrences (all)	6			
DYSPHAGIA				
alternative dictionary used: MedDRA 17				

subjects affected / exposed	6 / 34 (17.65%)		
occurrences (all)	10		
FLATULENCE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 34 (11.76%)		
occurrences (all)	4		
HAEMORRHOIDS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
MOUTH ULCERATION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
NAUSEA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	18 / 34 (52.94%)		
occurrences (all)	31		
RECTAL HAEMORRHAGE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
STOMATITIS			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	13 / 34 (38.24%)		
occurrences (all)	19		
VOMITING			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 34 (29.41%)		
occurrences (all)	16		
Skin and subcutaneous tissue disorders			
ALOPECIA			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	4 / 34 (11.76%)			
occurrences (all)	4			
DRY SKIN				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	7 / 34 (20.59%)			
occurrences (all)	8			
ERYTHEMA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences (all)	1			
HYPERHIDROSIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	3			
HYPERKERATOSIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	2			
NAIL DISORDER				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	3 / 34 (8.82%)			
occurrences (all)	3			
PALMAR-PLANTAR ERYTHRODYSAESTHESIA SYNDROME				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	10 / 34 (29.41%)			
occurrences (all)	14			
PIGMENTATION DISORDER				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences (all)	1			
PRURITUS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	3			

RASH			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	4		
RASH GENERALISED			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
Renal and urinary disorders			
DYSURIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	3		
POLLAKIURIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 34 (2.94%)		
occurrences (all)	1		
PROTEINURIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 34 (14.71%)		
occurrences (all)	6		
Endocrine disorders			
HYPOTHYROIDISM			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 34 (23.53%)		
occurrences (all)	9		
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 34 (14.71%)		
occurrences (all)	5		
BACK PAIN			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 34 (11.76%)		
occurrences (all)	4		

JOINT SWELLING				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	2			
MUSCLE SPASMS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	3 / 34 (8.82%)			
occurrences (all)	5			
MUSCULAR WEAKNESS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	3			
MUSCULOSKELETAL CHEST PAIN				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	3 / 34 (8.82%)			
occurrences (all)	4			
MUSCULOSKELETAL PAIN				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	2			
MYALGIA				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	5 / 34 (14.71%)			
occurrences (all)	6			
NECK PAIN				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences (all)	0			
PAIN IN EXTREMITY				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	4			
Infections and infestations				

CYSTITIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	3 / 34 (8.82%)			
occurrences (all)	3			
GASTROINTESTINAL INFECTION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences (all)	0			
HERPES ZOSTER				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences (all)	0			
LOWER RESPIRATORY TRACT INFECTION				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	2 / 34 (5.88%)			
occurrences (all)	2			
NASOPHARYNGITIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences (all)	1			
ORAL CANDIDIASIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences (all)	1			
RASH PUSTULAR				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	0 / 34 (0.00%)			
occurrences (all)	0			
RHINITIS				
alternative dictionary used: MedDRA 17				
subjects affected / exposed	1 / 34 (2.94%)			
occurrences (all)	1			
UPPER RESPIRATORY TRACT INFECTION				
alternative dictionary used: MedDRA 17				

subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
URINARY TRACT INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	3		
VIRAL INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
VIRAL UPPER RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
ANOREXIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	13 / 34 (38.24%)		
occurrences (all)	20		
DECREASED APPETITE			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	3		
HYPERCALCAEMIA			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 34 (5.88%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 September 2005	Radiological tumour assessment at visit 15 was made optional for patients with progressive disease, or unconfirmed partial or complete response at visit 11. For all other patients the visit 15 radiological assessment was removed.
27 September 2005	Synopsis, secondary objective #1 and efficacy variables; Section 4.2, secondary objective #1; Study Plan in Table 2; Section 5.5.3.2, objective tumour response rate
27 September 2005	The recording of chemotherapy following discontinuation was removed.
27 September 2005	Haematocrit was added to the panel of haematology assessments.
04 December 2006	The first secondary objective was split into 2 separate objectives.
04 December 2006	An additional exploratory objective was added to investigate the relationship between hypertension and the effects of AZD2171 on angiogenesis biomarkers and clinical efficacy
04 December 2006	The target patient population text was amended to include the wording 'with the exception of prostate cancer'
04 December 2006	The grouping of the primary outcome variables under the heading 'efficacy' was corrected
04 December 2006	Time-point information was added to the blood pressure safety variables
04 December 2006	The wording detailing when the radiological and clinical tumour assessments were performed was changed from 'within 3 weeks of the first dose of AZD2171' to 'within 3 weeks prior to randomisation'. The wording detailing when pregnancy tests were to be performed was changed from 'within 3 days prior to randomisation' to within 3 days prior to first study drug administration'
04 December 2006	The text detailing the method of assessment of blood pressure changes was amended to include the wording 'and when clinically indicated'.
04 December 2006	The wording detailing the timings for the assessment of ambulatory blood pressure was amended.
04 December 2006	The following sentence: 'The 95% CIs for both variables have also been produced and will be used as a sensitivity analysis' was added to the text detailing the analysis of the primary variables.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported