Clinical trial results:
Phase II Study of Weekly Cabazitaxel for Advanced Prostate Cancer in "Unfit" Hormone-Refractory Patients Previously Treated with Docetaxel.

Summary

EudraCT number	2011-004627-12
Trial protocol	ES
Global end of trial date	29 April 2016

Results information

Result version number	v1 (current)
This version publication date	14 November 2021
First version publication date	14 November 2021

Trial information

Trial identification

Sponsor protocol code	CABASEM-SOGUG

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01518283
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	SOGUG - Spanish Oncology Genitourinary Group
Sponsor organisation address	Calle Velázquez, 7, planta 3, Madrid , Spain, 28001
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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	29 April 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 April 2016
Global end of trial reached?	Yes
Global end of trial date	29 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluate the activity of the weekly administration of cabazitaxel as time to PSA progression according to the PCCTWG II criteria.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 January 2012
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	Spain: 74
Worldwide total number of subjects	74
EEA total number of subjects	74

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)	9
From 65 to 84 years	5
85 years and over	60

Subject disposition

Recruitment

Recruitment details:

Patients were recruited in the study from 10th May 2012 until 24th April 2014.

Pre-assignment

Screening details:

Patients included in the study had to show histologically or cytologically confirmed adenocarcinoma of the prostate, undergone castration by orchiectomy or by LHRH agonists, clinical or radiological documented disease progression, metastasic disease, life expectancy of at least 12 weeks, ECOG-PS 2 and adequate organ function.

Pre-assignment period milestones

Number of subjects started	74
Number of subjects completed	70

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Screening failure: 4

Period 1

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

Blinding implementation details:

Not applicable

Arms

Arm title	Study treatment

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Cabazitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cabazitaxel 10 mg/week

Number of subjects in period 1[1]	Study treatment
Started	70
Completed	0
Not completed	70
Consent withdrawn by subject	1
Physician decision	4

Patient decision	2
Protocol non-compliance	1
Disease progression	38
Toxicity	8
Clinical deterioration	3
Adverse event not related with treatment	8
Exitus	3
Delay in administration upper to 15 days	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: Four enrolled patients were screening failure and they did not receive study treatment.

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	70	70	
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)	8	8	
From 65-84 years	4	4	
85 years and over	58	58	
Age continuous Units: years			
median	73.9		
full range (min-max)	54.6 to 85.7	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	70	70	
ECOG-PS Units: Subjects			
0)	9	9	
1)	11	11	
2)	50	50	
Histological diagnosis Units: Subjects			
Prostate adenocarcinoma	62	62	
Acinar adenocarcinoma of prostate	4	4	
Prostate carcinoma	2	2	
Ductal adenocarcinoma	1	1	
Invasive adenocarcinoma of prostate	1	1	
Histological diagnosis: Acinar adenocarcinoma of prostate Units: Subjects			
Yes	4	4	
No	66	66	
Histological diagnosis. Prostate carcinoma Units: Subjects			

Yes	2	2	
No	68	68	
TNM at diagnosis: T Units: Subjects			
T2	16	16	
T3	24	24	
T4	5	5	
Tx	17	17	
Not available	8	8	
TNM at diagnosis: N Units: Subjects			
N0	28	28	
N1	14	14	
N2	1	1	
NX	18	18	
Not available	9	9	
TNM at diagnosis: M Units: Subjects			
M0	35	35	
M1	30	30	
MX	3	3	
Not available	2	2	
TNM at diagnosis: Stage Units: Subjects			
II	10	10	
III	12	12	
IV	37	37	
Not available	11	11	
Current TNM: T Units: Subjects			
T2	10	10	
T3	21	21	
T4	9	9	
Tx	21	21	
Not available	9	9	
Current TNM: N Units: Subjects			
N0	21	21	
N1	23	23	
N2	1	1	
NX	15	15	
Not available	10	10	
Current TNM: M Units: Subjects			
M1	70	70	
Current TNM: Stage Units: Subjects			
IV	69	69	
Not available	1	1	
Gleason score Units: Subjects			

<8	35	35	
≥8	32	32	
Not available	3	3	
Previous therapy: Radiotherapy Units: Subjects			
Yes	41	41	
No	29	29	
Weight Units: Kg			
median	78.9		
full range (min-max)	46.0 to 118.0	-	
Height Units: Cm			
median	168.0		
full range (min-max)	152.0 to 191.0	-	
Heart rate Units: lpm			
median	78.0		
full range (min-max)	59.0 to 116.0	-	
Systolic pressure Units: mmHg			
median	129.0		
full range (min-max)	88.0 to 173.0	-	
Dyastolic pressure Units: mmHg			
median	76.0		
full range (min-max)	58.0 to 114.0	-	
Time since initial diagnosis Units: Months			
median	71.1		
full range (min-max)	7.0 to 241.9	-	
Number of previous lines of treatment Units: Lines of treatment			
median	2.0		
full range (min-max)	1.0 to 5.0	-	

End points

End points reporting groups

Reporting group title	Study treatment

Reporting group description: -

Primary: Biochemical progression-free survival at 12 weeks

End point title	Biochemical progression-free survival at 12 weeks[1]

End point description:

Biochemical progression-free survival was defined as the time elapsed, in months, from the time the patient start in the study until progression (PSA or radiological progression) or death for any cause.

End point type	Primary

End point timeframe:

12 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses have been performed. Phase II non-comparative study

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Percentage				
number (confidence interval 95%)	68.6 (55.7 to 81.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Biochemical progression-free survival

End point title	Biochemical progression-free survival

End point description:

Biochemical progression-free survival was defined as the time elapsed, in months, from the time the patient start in the study until progression (PSA or radiological progression) or death for any cause.

End point type	Secondary

End point timeframe:

Every 12 weeks

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Months				
median (confidence interval 95%)	4.05 (2.7 to 5.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Biochemical response rate 30%

End point title	Biochemical response rate 30%

End point description:

Biochemical response rate 30% has been defined as a reduction in PSA concentration greater than 30% from baseline.

End point type	Secondary

End point timeframe:

Every 4 weeks

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: % of subjects				
number (not applicable)				
Response	42.9			
No response	57.1			

Statistical analyses

No statistical analyses for this end point

Secondary: Biochemical response rate 50%

End point title	Biochemical response rate 50%

End point description:

Biochemical response rate 50% has been defined as a reduction in PSA concentration greater than 50% from baseline.

End point type	Secondary

End point timeframe:

Every 4 weeks

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: % of subjects				
number (not applicable)				
Response	34.3			
No response	65.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Biochemical response rate 80%

End point title	Biochemical response rate 80%

End point description:

Biochemical response rate 80% has been defined as a reduction in PSA concentration greater than 80% from baseline.

End point type	Secondary

End point timeframe:

Every 4 weeks

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: % of subjects				
number (not applicable)				
Response	10.0			
No Response	90.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate

End point title	Objective response rate

End point description:

Objective response has been calculated taking into account patients with complete response or partial response to treatment.

End point type	Secondary

End point timeframe:

Every 12 weeks

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: % of subjects				
number (confidence interval 95%)	5.7 (0.3 to 11.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival

End point description:

Overall survival was defined as the time elapsed, in months, from the time the patient start into the study until death for any cause.

End point type	Secondary

End point timeframe:

Every 12 weeks

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: Months				
median (confidence interval 95%)	12.632 (8.2 to 17.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pain response according to BPI

End point title	Pain response according to BPI

End point description:

Pain response is defined as an increase of ≥ 2 points from baseline, with no increase in the analgesic score, or a ≥ 50% analgesic use reduction without increased pain, for at least 3 weeks with respect to the lowest value measured according to the BPI scale.

End point type	Secondary

End point timeframe:

At baseline

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	66			
Units: Score				
median (full range (min-max))	3.6 (0.0 to 8.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of CTC response and progressión-free survival

End point title	Correlation of CTC response and progressión-free survival

End point description:

CTC response has been defined as a decrease in the absolute CTC value by at least 30% between the baseline assessment and the respectively timeframe. This value has been calculated based on the total number of evaluated patients (N=32 patients; Responders 19 patients; Non-responders 13 patients)

There are statistically significant differences between responders and non-responders (P-value <0.013).

End point type	Secondary

End point timeframe:

At week 4

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Months				
median (confidence interval 95%)				
Non-responders (13 patients)	3.06 (2.48 to 3.64)			
Responders (19 patients)	5.79 (3.69 to 7.89)			

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation of CTC response and Overall survival

End point title	Correlation of CTC response and Overall survival

End point description:

CTC response has been defined as a decrease in the absolute CTC value by at least 30% between the baseline assessment and the respectively timeframe. This value has been calculated based on the total

number of evaluated patients (N=32 patients; Responders 19 patients; No responders 13 patients).

There are no statistically significant differences between responders and non-responders.

End point type	Secondary
End point timeframe: At week 4	

End point values	Study treatment			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Months				
median (confidence interval 95%)				
Non-responders (13 patients) Responders (19 patients)	7.20 (5.66 to 8.75) 15.86 (9.50 to 22.21)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Until the end of treatment study

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Overall trial

Reporting group description: -

Serious adverse events	Overall trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	33 / 70 (47.14%)		
number of deaths (all causes)	59		
number of deaths resulting from adverse events	3		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder neoplasm			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Thromboembolic event			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombosis venous deep			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Nervous system disorders			
Spinal cord compression			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hepatic encephalopathy			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Febrile syndrome			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Malaise			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Fever			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdomen mimicking acute			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mucositis			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Rectorrhagia			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bowel obstruction			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal subobstruction			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cyclic vomiting syndrome			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pulmonary thromboembolism			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease exacerbation			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Hematuria			
subjects affected / exposed	3 / 70 (4.29%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Acute renal failure			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Renal function aggravated			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			

subjects affected / exposed	5 / 70 (7.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal insufficiency			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Lumbar pain			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Oral cavity infection			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory infection			
subjects affected / exposed	4 / 70 (5.71%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		

Sepsis			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Flu			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyponatremia			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 70 (92.86%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 70 (8.57%)		
occurrences (all)	7		
Hypotension			
subjects affected / exposed	3 / 70 (4.29%)		
occurrences (all)	3		
Pallor			
subjects affected / exposed	3 / 70 (4.29%)		
occurrences (all)	3		
General disorders and administration site conditions			

Asthenia subjects affected / exposed occurrences (all)	53 / 70 (75.71%) 148		
Oedema peripheral subjects affected / exposed occurrences (all)	7 / 70 (10.00%) 10		
Mucosal inflammation subjects affected / exposed occurrences (all)	4 / 70 (5.71%) 4		
General physical health deterioration subjects affected / exposed occurrences (all)	3 / 70 (4.29%) 3		
Pain subjects affected / exposed occurrences (all)	15 / 70 (21.43%) 16		
Respiratory, thoracic and mediastinal disorders			
Catarrh subjects affected / exposed occurrences (all)	9 / 70 (12.86%) 12		
Dysphonia subjects affected / exposed occurrences (all)	3 / 70 (4.29%) 3		
Dyspnoea subjects affected / exposed occurrences (all)	9 / 70 (12.86%) 11		
Epistaxis subjects affected / exposed occurrences (all)	4 / 70 (5.71%) 4		
Cough subjects affected / exposed occurrences (all)	3 / 70 (4.29%) 3		
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	5 / 70 (7.14%) 5		
Investigations			

Blood creatinine increased			
subjects affected / exposed	3 / 70 (4.29%)		
occurrences (all)	3		
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	7 / 70 (10.00%)		
occurrences (all)	8		
Dizziness			
subjects affected / exposed	6 / 70 (8.57%)		
occurrences (all)	7		
Peripheral neuropathy			
subjects affected / exposed	5 / 70 (7.14%)		
occurrences (all)	7		
Headache			
subjects affected / exposed	4 / 70 (5.71%)		
occurrences (all)	5		
Neurotoxicity			
subjects affected / exposed	6 / 70 (8.57%)		
occurrences (all)	6		
Paraesthesia			
subjects affected / exposed	8 / 70 (11.43%)		
occurrences (all)	8		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	10 / 70 (14.29%)		
occurrences (all)	29		
Leukopenia			
subjects affected / exposed	4 / 70 (5.71%)		
occurrences (all)	4		
Neutropenia			
subjects affected / exposed	3 / 70 (4.29%)		
occurrences (all)	8		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	31 / 70 (44.29%)		
occurrences (all)	73		
Dyspepsia			

subjects affected / exposed	5 / 70 (7.14%)		
occurrences (all)	9		
Abdominal pain			
subjects affected / exposed	5 / 70 (7.14%)		
occurrences (all)	7		
Constipation			
subjects affected / exposed	14 / 70 (20.00%)		
occurrences (all)	24		
Nausea			
subjects affected / exposed	22 / 70 (31.43%)		
occurrences (all)	31		
Lower abdominal pain			
subjects affected / exposed	3 / 70 (4.29%)		
occurrences (all)	3		
Upper abdominal pain			
subjects affected / exposed	8 / 70 (11.43%)		
occurrences (all)	9		
Abdominal discomfort			
subjects affected / exposed	4 / 70 (5.71%)		
occurrences (all)	4		
Vomiting			
subjects affected / exposed	13 / 70 (18.57%)		
occurrences (all)	18		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	3 / 70 (4.29%)		
occurrences (all)	3		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	4 / 70 (5.71%)		
occurrences (all)	4		
Haematuria			
subjects affected / exposed	14 / 70 (20.00%)		
occurrences (all)	18		
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	20 / 70 (28.57%)		
occurrences (all)	32		
Arthralgia			
subjects affected / exposed	7 / 70 (10.00%)		
occurrences (all)	7		
Pain in extremity			
subjects affected / exposed	7 / 70 (10.00%)		
occurrences (all)	12		
Groin pain			
subjects affected / exposed	4 / 70 (5.71%)		
occurrences (all)	4		
Bone pain			
subjects affected / exposed	3 / 70 (4.29%)		
occurrences (all)	3		
Muscular weakness			
subjects affected / exposed	4 / 70 (5.71%)		
occurrences (all)	5		
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	3 / 70 (4.29%)		
occurrences (all)	4		
Respiratory tract infection			
subjects affected / exposed	7 / 70 (10.00%)		
occurrences (all)	7		
Urinary tract infection			
subjects affected / exposed	8 / 70 (11.43%)		
occurrences (all)	9		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	33 / 70 (47.14%)		
occurrences (all)	62		
Hypercholesterolemia			
subjects affected / exposed	5 / 70 (7.14%)		
occurrences (all)	7		
Hyperglycaemia			

subjects affected / exposed	4 / 70 (5.71%)		
occurrences (all)	9		
Hypocalcaemia			
subjects affected / exposed	4 / 70 (5.71%)		
occurrences (all)	4		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No statistical analyses have been performed. Phase II non-comparative study

Notes: