Clinical trial results:
Abiraterona acetate maintenance in combination with docetaxel after disease progression to abiraterona acetate in metastatic castration resistant prostate cancer. Randomized phase II study.

Summary

EudraCT number	2013-003811-23
Trial protocol	ES
Global end of trial date	08 June 2020

Results information

Result version number	v1 (current)
This version publication date	16 October 2021
First version publication date	16 October 2021

Trial information

Trial identification

Sponsor protocol code	ABIDO

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02036060
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
Public contact	Clinical Operations Department, APICES SOLUCIONES, S.L., +34 91 816 68 04 Ext 103, ana.moreno@apices.es
Scientific contact	Clinical Operations Department, APICES SOLUCIONES, S.L., +34 91 816 68 04 Ext103, ana.moreno@apices.es

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	17 June 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 June 2020
Global end of trial reached?	Yes
Global end of trial date	08 June 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

12 months radiologic progression free survival of two arms of treatment (docetaxel + prednisone + abiraterone or docetaxel + prednisone) in metastatic castration resistant prostate cancer

Protection of trial subjects:

Randomization

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 February 2014
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: 148
Worldwide total number of subjects	148
EEA total number of subjects	148

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)	39
From 65 to 84 years	101
85 years and over	8

Subject disposition

Recruitment

Recruitment details:

Patients were recruited in the study from 07th February 2014 until 27th July 2016.

Patients were randomised in the study from 30th July 2014 until 26th February 2019.

Pre-assignment

Screening details:

Patients included in the study had had to show histologically or cytologically confirmed adenocarcinoma of the prostate, be asymptomatic or mildly symptomatic from prostate cancer, received previous anti-androgen therapy and progression after withdrawal, have a Life expectancy of at least 6 months, ECOG PS of 0-1 and adequate organ function.

Pre-assignment period milestones

Number of subjects started	148
Number of subjects completed	94

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Pre-randomisation loss (94 randomized): 54

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A: Docetaxel + Prednisone + abiraterone

Arm description:

Docetaxel 75 mg/m2 + prednisone 10 mg/d + abiraterone 1000 mg/d in 21 day cycles.

Arm type	Experimental
Investigational medicinal product name	Abiraterone acetate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 tables of 250 mg/day (1000 mg)

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

75 mg/m2 every 21 days

Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet

Routes of administration	Oral use

Dosage and administration details:

10 mg daily

Arm title	Arm B: Docetaxel + Prednisone

Arm description:

Docetaxel 75 mg/m2 plus prednisone 10 mg/d in 21 day cycles.

Arm type	Active comparator
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

75 mg/m2 every 21 days

Investigational medicinal product name	Prednisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg daily

Number of subjects in period 1[1]	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone
Started	47	47
Completed	22	20
Not completed	25	27
Physician decision	1	-
Disease progression	14	14
Development of other intercurrent diseases	1	4
Unacceptable toxicity	5	7
Exitus	4	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: During stage I of study, 148 patients were included. Prior to the start of Phase II, 54 patients were pre-randomisation failures, resulting in a total of 94 patients participating in stage II of the study.

Baseline characteristics

Reporting groups	
Reporting group title	Arm A: Docetaxel + Prednisone + abiraterone
Reporting group description:	
Docetaxel 75 mg/m2 + prednisone 10 mg/d + abiraterone 1000 mg/d in 21 day cycles.	
Reporting group title	Arm B: Docetaxel + Prednisone
Reporting group description:	
Docetaxel 75 mg/m2 plus prednisone 10 mg/d in 21 day cycles.	

Reporting group values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone	Total
Number of subjects	47	47	94
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)	13	19	32
From 65-84 years	31	28	59
85 years and over	3	0	3
Age continuous Units: years			
median	70.0	68.0	
full range (min-max)	51.0 to 85.0	45.0 to 84.0	-
Gender categorical Units: Subjects			
Female	0	0	0
Male	47	47	94
Ethnics Units: Subjects			
Caucasian	46	46	92
African	0	1	1
Arab	1	0	1
Risk behaviours: Tobacco Units: Subjects			
Yes	9	11	20
No	36	36	72
Not available	2	0	2
Risk behaviours: Alcohol Units: Subjects			
Yes	3	9	12
No	42	38	80
Not available	2	0	2

Intercurrent disease Units: Subjects			
Yes	41	40	81
No	6	7	13
ECOG-PS Units: Subjects			
0)	23	16	39
1)	21	26	47
2)	3	5	8
TNM: Stage at initial diagnosis Units: Subjects			
I)	2	0	2
II)	7	4	11
IIA)	1	0	1
III)	11	7	18
IV)	22	26	48
Not available	4	10	14
Gleason score at initial diagnosis Units: Subjects			
<8	19	19	38
≥8	26	20	46
Not available	2	8	10
Previous therapy: Radical prostatectomy Units: Subjects			
Yes	14	10	24
No	33	37	70
Previous therapy: Radical radiotherapy Units: Subjects			
Yes	11	14	25
No	36	33	69
Tumor location: Bone Units: Subjects			
Yes	40	40	80
No	7	7	14
Tumor location: Lymph nodes Units: Subjects			
Yes	27	30	57
No	20	17	37
Tumor location: Liver Units: Subjects			
Yes	4	4	8
No	43	43	86
Number of locations per patient Units: Subjects			
1)	22	17	39
2)	18	19	37
3)	5	6	11
4)	1	3	4
Non Evaluable	1	2	3

Height			
Units: Cm			
median	168.3	169.0	
full range (min-max)	154.0 to 196.0	153.0 to 182.0	-
Weight			
Units: Kg			
median	79.3	82.0	
full range (min-max)	63.0 to 116.6	53.5 to 117.0	-
Time since initial diagnosis			
Units: Months			
median	48.8	39.6	
full range (min-max)	7.8 to 207.3	6.8 to 188.6	-
Time since metastasic diagnosis			
Units: Months			
median	11.7	14.9	
full range (min-max)	0.2 to 137.3	0.5 to 113.8	-
Treatment duration of abiraterone phase I			
Units: Months			
median	12.1	13.6	
full range (min-max)	2.6 to 60.0	2.8 to 39.9	-
Number of cycles phase II			
Units: Cycles			
median	8.0	8.0	
full range (min-max)	1.0 to 10.0	1.0 to 10.0	-
Relative dose intensity of docetaxel			
Units: Percentage			
median	87	87	
full range (min-max)	50 to 96	63 to 100	-
Relative dose intensity of abiraterone phase II (only Arm A)			
Units: Percentage			
median	94	0	
full range (min-max)	50 to 101	0 to 0	-
PSA at baseline			
Units: ng/ml			
median	73	34	
full range (min-max)	1 to 1401	0 to 4256	-

End points

End points reporting groups

Reporting group title	Arm A: Docetaxel + Prednisone + abiraterone
Reporting group description:	
Docetaxel 75 mg/m2 + prednisone 10 mg/d + abiraterone 1000 mg/d in 21 day cycles.	
Reporting group title	Arm B: Docetaxel + Prednisone
Reporting group description:	
Docetaxel 75 mg/m2 plus prednisone 10 mg/d in 21 day cycles.	

Primary: Radiological progression-free survival at 12 Months

End point title	Radiological progression-free survival at 12 Months[1]

End point description:

Radiological progression-free survival was defined as the time elapsed, in months, from the time the patient is randomised into the study until the patient progresses according to RECIST criteria and PCWG2 criteria or dies for any cause.

End point type	Primary

End point timeframe:

Every 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	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	47		
Units: Percentage				
number (confidence interval 95%)	34.9 (20.7 to 49.2)	33.9 (19.5 to 48.3)		

Attachments (see zip file)	rSLP.png

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 was randomised into the study until death for any cause.

End point type	Secondary

End point timeframe:

Every 12 weeks

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	47		
Units: Months				
median (confidence interval 95%)	17.368 (14.058 to 20.679)	16.908 (9.792 to 24.023)		

Statistical analyses

No statistical analyses for this end point

Secondary: Radiological progression-free survival of study arms

End point title	Radiological progression-free survival of study arms

End point description:

Radiological progression-free survival was defined as the time elapsed, in months, from the time the patient is randomised into the study until the patient progresses according to RECIST criteria and PCWG2 criteria or dies for any cause.

End point type	Secondary

End point timeframe:

Every 12 weeks

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	47		
Units: Months				
median (confidence interval 95%)	8.816 (5.948 to 11.684)	9.770 (7.234 to 12.305)		

Statistical analyses

No statistical analyses for this end point

Secondary: PSA progression free survival

End point title	PSA progression free survival

End point description:

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

End point type	Secondary

End point timeframe:

Every 12 weeks

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	47		
Units: Months				
median (confidence interval 95%)	5.428 (3.614 to 7.241)	5.39 (4.003 to 5.928)		

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 has been defined as a reduction in PSA concentration of greater than 50% from the baseline stage II visit (first available determination prior to initiation of docetaxel treatment)

End point type	Secondary

End point timeframe:

Everyb 4 weeks

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	47		
Units: % of Subjects				
Response	64	47		
No response	36	53		

Statistical analyses

No statistical analyses for this end point

Secondary: Biochemical response rate 90%

End point title	Biochemical response rate 90%

End point description:

Biochemical response has been defined as a reduction in PSA concentration of greater than 50% from the baseline stage II visit (first available determination prior to initiation of docetaxel treatment).

End point type	Secondary

End point timeframe:

Every 4 weeks

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	47		
Units: % of subjects				
Response	21	11		
No response	79	89		

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 which has been response to treatment. In this case, 7 patients of Arm A and 3 patients of Arm B had a partial response to treatment.

End point type	Secondary

End point timeframe:

Every 12 weeks

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	47		
Units: % of subjects				
number (confidence interval 95%)	14.9 (4.7 to 25.1)	6.4 (0 to 13.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline in the FACT-P total score (SD)b

End point title	Mean change from baseline in the FACT-P total score (SD)b

End point description:

The FACT-P scale includes 5 fields corresponding the following ranges: general physical status (range 0-28), family and social environment (range 0-28), emotional status (range 0-24), functioning ability (range 0-28) and prostate cancer specific symptoms (range 0-48); plus a total score (range 0-156). The higher the score, the better the quality of life.

End point type	Secondary

End point timeframe:

Every 4 weeks

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	31		
Units: Score				
median (full range (min-max))	-0.5 (-69.3 to 41.3)	-1.3 (-38.6 to 42.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to skeletal event

End point title	Time to skeletal event

End point description:

Time to skeletal event is defined has been defined as the time elapsed from randomization until the onset of skeletal event. The following were considered skeletal events: pathological fracture, spinal cord compression, radiotherapy or bone surgery, and hypercalcaemia of bone metastasis, occurring after randomisation in phase II. 9 patients (4 of Arm A and 5 of Arm B)shown skeletal events during stage II of the study.

End point type	Secondary

End point timeframe:

Every 12 weeks.

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	5		
Units: Months				
median (full range (min-max))	1.2 (0.7 to 6.1)	7.8 (4.0 to 8.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to opiate initiation

End point title	Time to opiate initiation

End point description:

Time to opiate initiation was defined as the time elapsed, in months, from the patient was randomised in the study until opioide treatment initiation for oncologic pain. 35 patients (18 in arm A and 17 in arm B) started treatment with newly prescribed opioids. Four patients in both arms started opioid treatment on the same day they were randomised in stage II of the study.

End point type	Secondary

End point timeframe:

Every 4 weeks

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	17		
Units: Months				
median (full range (min-max))	3.2 (0.0 to 14.7)	1.4 (0.0 to 5.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Worsening of pain according to BPI-SF

End point title	Worsening of pain according to BPI-SF

End point description:

Worsening of pain has been defined as an increase of at least 2 points, with respect to the lowest value measured during stage II, in item 3 of the BPI scale.

End point type	Secondary

End point timeframe:

Every 4 weeks

End point values	Arm A: Docetaxel + Prednisone + abiraterone	Arm B: Docetaxel + Prednisone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	47		
Units: Patients				
Yes	25	26		
No	22	21		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During phase II of study treatment (After randomization)

Adverse event reporting additional description:

Adverse events are shown in two groups depending on the treatment arm in which they occurred, differentiated as follows:

Arm A: Docetaxel + prednisone + Abiraterone.
Arm B: Docetaxel + prednisone

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Arm A: Docetaxel + Prednisone + Abiraterone
Reporting group description: -	
Reporting group title	Arm B: Docetaxel + Prednisone
Reporting group description: -	
Reporting group title	Total

Reporting group description: -

Serious adverse events	Arm A: Docetaxel + Prednisone + Abiraterone	Arm B: Docetaxel + Prednisone	Total
Total subjects affected by serious adverse events			
subjects affected / exposed	31 / 47 (65.96%)	20 / 47 (42.55%)	51 / 94 (54.26%)
number of deaths (all causes)	37	29	66
number of deaths resulting from adverse events	6	1	7
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastrointestinal stromal tumour	Additional description: Gastrointestinal stromal tumour grade 3		
subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Phlebitis	Additional description: Phlebitis grade 3		
subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Nephrostomy	Additional description: Nephrostomy grade 3		

subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transurethral resection of bladder tumor	Additional description: Transurethral resection of bladder tumor grade 2		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
General physical health deterioration	Additional description: 1 General physical health deterioration grade 4, 1 grade 3 and 1 grade 2. General physical health deterioration grade 4 related with docetaxel. General physical health deterioration grade 3 related with abidaterone.		
subjects affected / exposed	3 / 47 (6.38%)	0 / 47 (0.00%)	3 / 94 (3.19%)
occurrences causally related to treatment / all	2 / 3	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General body pain	Additional description: General body pain grade 3		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fever	Additional description: Fever grade 1 related with abiraterone		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucositis	Additional description: Mucositis grade 3 related with docetaxel		
subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory insufficiency	Additional description: Acute respiratory insufficiency grade 5		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Chronic obstructive pulmonary disease exacerbation	Additional description: 2 Chronic obstructive pulmonary disease exacerbation grade 3		

subjects affected / exposed	0 / 47 (0.00%)	2 / 47 (4.26%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Neutrophil count decreased	Additional description: Neutrophil count decreased grade 4 related with docetaxel		
subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GGT increased	Additional description: GGT increased grade 4		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture	Additional description: 2 Hip fracture grade 3		
subjects affected / exposed	0 / 47 (0.00%)	2 / 47 (4.26%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture	Additional description: Rib fracture grade 2		
subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung injury	Additional description: Lung injury grade 3		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute cardiac event	Additional description: Acute cardiac event grade 5 related with abidaterone and docetaxel		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
Cardiac failure congestive	Additional description: Cardiac failure congestive grade 3 related with abiraterone and docetaxel		

subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain stem stroke	Additional description: Brain stem stroke Grade 5		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Spinal cord compression	Additional description: 1 Spinal cord compression Grade 3 and 1 Grade 5		
subjects affected / exposed	2 / 47 (4.26%)	0 / 47 (0.00%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hepatic encephalopathy	Additional description: Hepatic encephalopathy grade 4 related with docetaxel		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia Grade 4		
subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia	Additional description: 2 Leukopenia grade 4 related with docetaxel		
subjects affected / exposed	1 / 47 (2.13%)	1 / 47 (2.13%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	1 / 1	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia	Additional description: 2 Neutropenia grade 3 (1 in Arm A and 1 in Arm B) and 20 grade 4 (18 in Arm A and 2 in Arm B). All related with docetaxel and one of them with abiraterone		
subjects affected / exposed	19 / 47 (40.43%)	3 / 47 (6.38%)	22 / 94 (23.40%)
occurrences causally related to treatment / all	19 / 19	3 / 3	22 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	Additional description: 8 febrile neutropenia grade 3 (2 in Arm A and 6 in Arm B) and 7 grade 4 (6 in Arm A and 1 in Arm B), all related with docetaxel.		
subjects affected / exposed	8 / 47 (17.02%)	7 / 47 (14.89%)	15 / 94 (15.96%)
occurrences causally related to treatment / all	8 / 8	7 / 7	15 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Diarrhoea	Additional description: 2 diarrohoea grade 3 related with docetaxel.		
subjects affected / exposed	0 / 47 (0.00%)	2 / 47 (4.26%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 0	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis leukopenic	Additional description: Enteritis leukopenic grade 4 related with docetaxel		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation	Additional description: Constipation grade 3		
subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric ischemia	Additional description: Mesenteric ischemia grade 5 related with docetaxel		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
Renal and urinary disorders			
Hematuria	Additional description: 5 Hematuria grade 3		
subjects affected / exposed	4 / 47 (8.51%)	1 / 47 (2.13%)	5 / 94 (5.32%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insufficiency renal	Additional description: Insufficiency renal grade 3		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Knee arthritis	Additional description: Knee arthritis Grade 3		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar pain	Additional description: Lumbar pain grade 3		

subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain	Additional description: Bone pain grade 3		
subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic bone pain	Additional description: Pelvic bone pain grade 3		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Influenza A virus infection	Additional description: Influenza A virus infection grade 3		
subjects affected / exposed	0 / 47 (0.00%)	1 / 47 (2.13%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory infection	Additional description: 2 Respiratory infection grade 3		
subjects affected / exposed	0 / 47 (0.00%)	2 / 47 (4.26%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection	Additional description: 2 Lower respiratory tract infection grade 3		
subjects affected / exposed	1 / 47 (2.13%)	1 / 47 (2.13%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: 1 Urinary tract infection grade 3 and 1 grade 2		
subjects affected / exposed	0 / 47 (0.00%)	2 / 47 (4.26%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary infection	Additional description: 2 Urinary infection grade 3		
subjects affected / exposed	0 / 47 (0.00%)	2 / 47 (4.26%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia	Additional description: 3 Pneumonia grade 3, 1 related with docetaxel		

subjects affected / exposed	3 / 47 (6.38%)	0 / 47 (0.00%)	3 / 94 (3.19%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: 1 Sepsis grade 3 (Arm A) and 1 grade 4 (Arm B). Sepsis grade 4 related with docetaxel.		
subjects affected / exposed	1 / 47 (2.13%)	1 / 47 (2.13%)	2 / 94 (2.13%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial sepsis	Additional description: Clostridial sepsis grade 3 related with docetaxel		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis	Additional description: Urosepsis grade 2		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock	Additional description: 1 Septic shock grade 3 (Arm A) and 2 grade 5 (1 in Arm A and 1 in Arm B). 1 shock septic grade 5 (Arm A) related with docetaxel.		
subjects affected / exposed	2 / 47 (4.26%)	1 / 47 (2.13%)	3 / 94 (3.19%)
occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 3
deaths causally related to treatment / all	1 / 1	0 / 1	1 / 2
Metabolism and nutrition disorders			
Fluid retention	Additional description: Fluid retention grade 3 related with docetaxel		
subjects affected / exposed	1 / 47 (2.13%)	0 / 47 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Arm A: Docetaxel + Prednisone + Abiraterone	Arm B: Docetaxel + Prednisone	Total
Total subjects affected by non-serious adverse events			
subjects affected / exposed	47 / 47 (100.00%)	44 / 47 (93.62%)	91 / 94 (96.81%)
Vascular disorders			
Hypertension			

subjects affected / exposed	3 / 47 (6.38%)	4 / 47 (8.51%)	7 / 94 (7.45%)
occurrences (all)	6	5	11
Hypotension			
subjects affected / exposed	4 / 47 (8.51%)	1 / 47 (2.13%)	5 / 94 (5.32%)
occurrences (all)	6	2	8
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	37 / 47 (78.72%)	34 / 47 (72.34%)	71 / 94 (75.53%)
occurrences (all)	94	83	177
General physical health deterioration			
subjects affected / exposed	4 / 47 (8.51%)	0 / 47 (0.00%)	4 / 94 (4.26%)
occurrences (all)	4	0	4
Pain			
subjects affected / exposed	5 / 47 (10.64%)	3 / 47 (6.38%)	8 / 94 (8.51%)
occurrences (all)	6	4	10
Thoracic pain			
subjects affected / exposed	3 / 47 (6.38%)	0 / 47 (0.00%)	3 / 94 (3.19%)
occurrences (all)	3	0	3
Oedema			
subjects affected / exposed	7 / 47 (14.89%)	0 / 47 (0.00%)	7 / 94 (7.45%)
occurrences (all)	8	0	8
Oedema peripheral			
subjects affected / exposed	11 / 47 (23.40%)	6 / 47 (12.77%)	17 / 94 (18.09%)
occurrences (all)	13	6	19
Fatigue			
subjects affected / exposed	3 / 47 (6.38%)	0 / 47 (0.00%)	3 / 94 (3.19%)
occurrences (all)	6	0	6
Mucosal inflammation			
subjects affected / exposed	13 / 47 (27.66%)	11 / 47 (23.40%)	24 / 94 (25.53%)
occurrences (all)	17	16	33
Pyrexia			
subjects affected / exposed	12 / 47 (25.53%)	9 / 47 (19.15%)	21 / 94 (22.34%)
occurrences (all)	13	11	24
Respiratory, thoracic and mediastinal disorders			

Catarrh			
subjects affected / exposed	4 / 47 (8.51%)	1 / 47 (2.13%)	5 / 94 (5.32%)
occurrences (all)	4	2	6
Dyspnoea			
subjects affected / exposed	6 / 47 (12.77%)	1 / 47 (2.13%)	7 / 94 (7.45%)
occurrences (all)	7	1	8
Cough			
subjects affected / exposed	4 / 47 (8.51%)	3 / 47 (6.38%)	7 / 94 (7.45%)
occurrences (all)	5	5	10
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 47 (4.26%)	4 / 47 (8.51%)	6 / 94 (6.38%)
occurrences (all)	2	4	6
Investigations			
Blood creatinine increased			
subjects affected / exposed	1 / 47 (2.13%)	3 / 47 (6.38%)	4 / 94 (4.26%)
occurrences (all)	5	8	13
Blood alkaline phosphatase increased			
subjects affected / exposed	8 / 47 (17.02%)	5 / 47 (10.64%)	13 / 94 (13.83%)
occurrences (all)	9	11	20
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	8 / 47 (17.02%)	13 / 47 (27.66%)	21 / 94 (22.34%)
occurrences (all)	12	17	29
Dizziness			
subjects affected / exposed	2 / 47 (4.26%)	4 / 47 (8.51%)	6 / 94 (6.38%)
occurrences (all)	2	4	6
Neuropathy peripheral			
subjects affected / exposed	7 / 47 (14.89%)	7 / 47 (14.89%)	14 / 94 (14.89%)
occurrences (all)	11	9	20
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 47 (0.00%)	4 / 47 (8.51%)	4 / 94 (4.26%)
occurrences (all)	0	6	6
Neurotoxicity			
subjects affected / exposed	4 / 47 (8.51%)	9 / 47 (19.15%)	13 / 94 (13.83%)
occurrences (all)	5	10	15
Paresthesia			

subjects affected / exposed	6 / 47 (12.77%)	4 / 47 (8.51%)	10 / 94 (10.64%)
occurrences (all)	12	6	18
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	13 / 47 (27.66%)	8 / 47 (17.02%)	21 / 94 (22.34%)
occurrences (all)	24	12	36
Leukopenia			
subjects affected / exposed	0 / 47 (0.00%)	3 / 47 (6.38%)	3 / 94 (3.19%)
occurrences (all)	0	3	3
Neutropenia			
subjects affected / exposed	18 / 47 (38.30%)	16 / 47 (34.04%)	34 / 94 (36.17%)
occurrences (all)	28	19	47
Febrile neutropenia			
subjects affected / exposed	8 / 47 (17.02%)	6 / 47 (12.77%)	14 / 94 (14.89%)
occurrences (all)	8	6	14
Eye disorders			
Excess tears			
subjects affected / exposed	9 / 47 (19.15%)	4 / 47 (8.51%)	13 / 94 (13.83%)
occurrences (all)	10	5	15
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	26 / 47 (55.32%)	24 / 47 (51.06%)	50 / 94 (53.19%)
occurrences (all)	46	67	113
Abdominal pain			
subjects affected / exposed	5 / 47 (10.64%)	2 / 47 (4.26%)	7 / 94 (7.45%)
occurrences (all)	8	4	12
Abdominal pain upper			
subjects affected / exposed	3 / 47 (6.38%)	2 / 47 (4.26%)	5 / 94 (5.32%)
occurrences (all)	3	2	5
Constipation			
subjects affected / exposed	14 / 47 (29.79%)	12 / 47 (25.53%)	26 / 94 (27.66%)
occurrences (all)	25	15	40
Nausea			
subjects affected / exposed	12 / 47 (25.53%)	12 / 47 (25.53%)	24 / 94 (25.53%)
occurrences (all)	17	25	42
Vomiting			

subjects affected / exposed	5 / 47 (10.64%)	8 / 47 (17.02%)	13 / 94 (13.83%)
occurrences (all)	7	13	20
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	19 / 47 (40.43%)	19 / 47 (40.43%)	38 / 94 (40.43%)
occurrences (all)	32	22	54
Nail dystrophy			
subjects affected / exposed	5 / 47 (10.64%)	3 / 47 (6.38%)	8 / 94 (8.51%)
occurrences (all)	5	4	9
Erythema			
subjects affected / exposed	3 / 47 (6.38%)	4 / 47 (8.51%)	7 / 94 (7.45%)
occurrences (all)	3	4	7
Eruption			
subjects affected / exposed	3 / 47 (6.38%)	2 / 47 (4.26%)	5 / 94 (5.32%)
occurrences (all)	3	2	5
Onycholysis			
subjects affected / exposed	6 / 47 (12.77%)	4 / 47 (8.51%)	10 / 94 (10.64%)
occurrences (all)	10	5	15
Pruritus			
subjects affected / exposed	1 / 47 (2.13%)	3 / 47 (6.38%)	4 / 94 (4.26%)
occurrences (all)	1	5	6
Skin toxicity			
subjects affected / exposed	3 / 47 (6.38%)	3 / 47 (6.38%)	6 / 94 (6.38%)
occurrences (all)	4	6	10
Nail disorder			
subjects affected / exposed	8 / 47 (17.02%)	7 / 47 (14.89%)	15 / 94 (15.96%)
occurrences (all)	15	13	28
Renal and urinary disorders			
Hematuria			
subjects affected / exposed	2 / 47 (4.26%)	3 / 47 (6.38%)	5 / 94 (5.32%)
occurrences (all)	5	4	9
Urinary retention			
subjects affected / exposed	3 / 47 (6.38%)	2 / 47 (4.26%)	5 / 94 (5.32%)
occurrences (all)	3	2	5
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	9 / 47 (19.15%)	10 / 47 (21.28%)	19 / 94 (20.21%)
occurrences (all)	12	13	25
Back pain			
subjects affected / exposed	15 / 47 (31.91%)	11 / 47 (23.40%)	26 / 94 (27.66%)
occurrences (all)	23	15	38
Pain in extremity			
subjects affected / exposed	8 / 47 (17.02%)	6 / 47 (12.77%)	14 / 94 (14.89%)
occurrences (all)	10	8	18
Musculoskeletal pain			
subjects affected / exposed	7 / 47 (14.89%)	7 / 47 (14.89%)	14 / 94 (14.89%)
occurrences (all)	13	10	23
Bone pain			
subjects affected / exposed	3 / 47 (6.38%)	4 / 47 (8.51%)	7 / 94 (7.45%)
occurrences (all)	4	5	9
Muscle spasms			
subjects affected / exposed	3 / 47 (6.38%)	0 / 47 (0.00%)	3 / 94 (3.19%)
occurrences (all)	3	0	3
Myalgia			
subjects affected / exposed	6 / 47 (12.77%)	4 / 47 (8.51%)	10 / 94 (10.64%)
occurrences (all)	7	6	13
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	17 / 47 (36.17%)	9 / 47 (19.15%)	26 / 94 (27.66%)
occurrences (all)	26	14	40

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 June 2015	Amendment 1: Protocol Vs 2.0
11 November 2019	Amendment 7: Protocol Vs 3.0
13 April 2020	Amendment 8: Protocol Vs 4.0

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported