Supplementary material

Supplementary methods

Statistical analysis

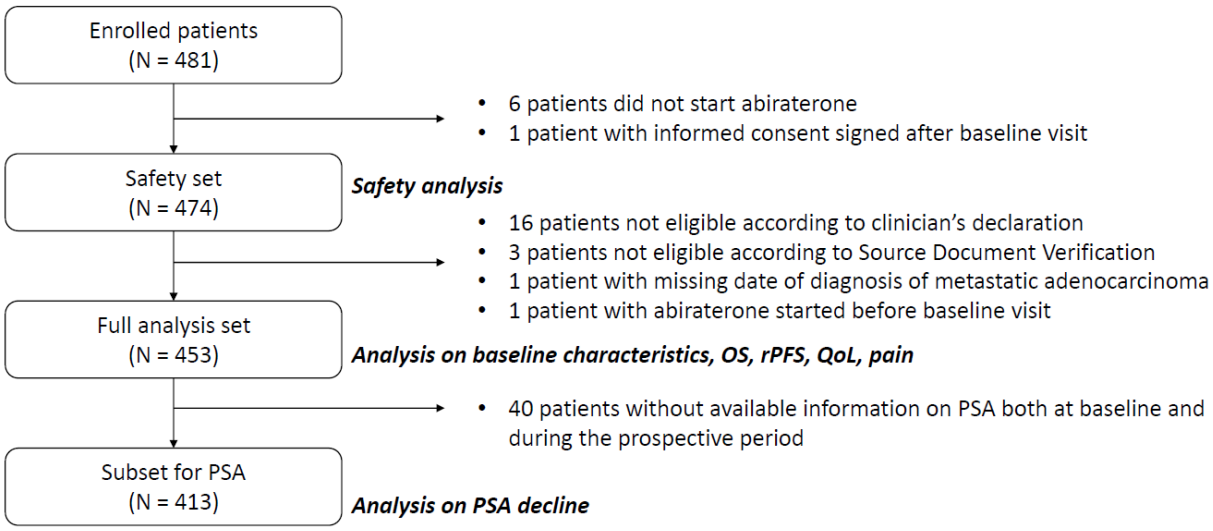
Outcomes of the ABItude study are radiographic progression free survival (rPFS), overall survival (OS), prostate-specific antigen (PSA) decline over time, duration of clinical benefit, duration of abiraterone treatment, abiraterone safety profile, patient-reported health related quality of life (HRQoL), patient-reported pain, use of opiates, second-line chemotherapy, time to visceral metastasis and adherence to abiraterone treatment. The current investigation presents the 2-year interim results of a subset of the major clinical and patient-reported outcomes; an extensive evaluation of all the study outcomes will occur at study completion, after 3 years of follow-up.

rPFS time was measured from the date of start of abiraterone treatment to the date of first radiographic disease progression or death for patients experiencing the event while on treatment with abiraterone. For patients alive and without radiographic progression, rPFS time was measured from the date of start of abiraterone treatment to the last date on abiraterone treatment. Radiographic progression was defined as the occurrence of bone scan progression by PCWG2 criteria, progression by computed tomography (CT) or magnetic resonance imaging (MRI) by modified Response Evaluation Criteria in Solid Tumors (RECIST) criteria. OS time was measured from the date of start of abiraterone treatment to the date of death (all-cause mortality) or the last date on study for alive patients. PSA decline was defined as at least one ≥50% reduction from baseline PSA during abiraterone treatment.

For the Brief Pain Inventory (BPI), and the EuroQol-5D (EQ-5D) data, only questionnaires filled in while the patient was still on treatment with abiraterone were considered. From BPI, "mean pain intensity" was calculated as the mean value of the scores given for items #3 (maximum intensity), #4 (minimum intensity), #5 (mean intensity), and #6 (present intensity) and "interference of pain" as the mean value of the seven questions of item #9; "worst pain intensity" was defined as the scored value of item #3 (maximum intensity). The theoretical range for each pain domain was 0-10 (with higher scores for a higher level of pain) [1]. Patients were defined as asymptomatic if their baseline score on item #3 of BPI was 0-1, mildly symptomatic if the score was 2-3, and symptomatic if the score was >3.

Continuous variables were presented as mean values ± standard deviation or median (interquartile range), and categorical variables as numbers and percentages. The Wilcoxon signed-rank test was used to test the changes over time in BPI, Visual Analog Scale (VAS) and EQ-5D-3L scores. The distribution of time-to-event variables was estimated using Kaplan-Meier product-limit survival curve. The median time to event and the 1- and 2-year probability of surviving were also calculated. Univariate and multivariable Cox proportional hazard models were used to evaluate the effect of selected characteristics on rPFS and OS. The following covariates were included in multivariable models: age, PSA at baseline, presence of comorbidities, visceral metastases, bone metastases and Eastern Cooperative Oncology Group (ECOG) performance status (PS). Hazard ratio estimates and corresponding 95% confidence intervals were obtained. Survival analyses were censored to a maximum of 24 months of observation.

Figure S1. Study flow-chart showing criteria violations and analysis sets.



OS: overall survival; PSA: prostate-specific antigen; QoL: quality of life; rPFS: radiographic progression free survival

Table S1. Safety profile[a].

	Patients (N=474)	
	N	%
Patients with at least one adverse event	231	48.7
Patients with at least one serious adverse event	84	17.7
Patients with at least one adverse reaction to AA	61	12.9
Patients with at least one serious adverse reaction to AA	8	1.7

AA: Abiraterone acetate.
[a]Adverse events occurred during treatment with AA were considered.

References

1. Basch E, Autio K, Ryan CJ, Mulders P, Shore N, Kheoh T et al. Abiraterone acetate plus prednisone versus prednisone alone in chemotherapy-naive men with metastatic castration-resistant prostate cancer: patient-reported outcome results of a randomised phase 3 trial. Lancet Oncol 2013; 14(12): 1193-1199.