817P Cabazitaxel treatment in metastatic castration-resistant prostate cancer (mCRPC) clinical trials compared to usual care in CAPRI: An observational study in the Netherlands

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Background: Cabazitaxel (CAB) has been shown in the TROPIC trial to improve overall survival (OS) in mCRPC patients after docetaxel (DOC). However clinical trial populations may not reflect the real world population. The objective is to compare patient characteristics and outcome of CAB within clinical trials and in standard of care (SOC) from data extracted from the CAPRI registry.

Methods: CRPC pts treated with CAB directly after DOC, before 1-1-2017, either within a clinical trial or as SOC were retrospectively identified and followed to 1-1-2018. For multivariable analyses, missing values were imputed by multiple imputation using the Monte Carlo Markov Chain method.

Results:

Table: 817P Baseline characteristics at start cabazitaxel (baseline period defined as 42 days before to 7 days after start of cabazitaxel). Total percentages may not equal 100 because of rounding.

	Cabazitaxel 1st line post-docetaxel (n = 173)		
	Usual care (n = 109)	Trial (n = 64)	p-value
Age (years) Median (IQR) ≥75 years (%)	68 (64-72) 17	67 (64-72) 13	0.502
Period on ADT (months) Median (IQR)	25 (18-37)	30 (19-45)	0.091
ALP (U/L) Median (IQR) Missing (%)	222 (100-360) 18	192 (97-366) 11	0.799
PSA (ug/L) Median (IQR) Missing (%)	200 (65-567) 12	209 (79-500) 8	0.711
Hemoglobin (mmol/L) Median (IQR) Missing (%)	7.1 (6.3-7.8) 17	7.7 (6.7-8.1) 11	0.029
LDH (U/L) Median (IQR) Missing (%)	328 (252-504) 26	268 (209-397 14)	0.010
ECOG performance (%) 0 1 >1 Missing	16 49 9 27	23 56 3 17	0.186
Visceral disease (%) No Yes Missing	29 19 52	45 11 44	0.038
Opioid use (%) No Yes Missing	23 28 50	41 27 33	0.140
Symptoms (%) No Yes Missing	6 78 16	17 72 11	0.033
Docetaxel cycles Median (IQR) Missing (%)	7 (5-10) 1	10 (7-10) 3	0.002
Time since last docetaxel dose (months) Median (IQR) <6 months (valid %) Missing (%)	2.2 (0.9-4.7) 86 5	3.9 (2.0-6.0) 74 5	0.001

From a total of 3,616 pts in the CAPRI database, we identified 356 pts treated with CAB, of which 173 pts were treated directly post-DOC. Trial pts had less symptoms and visceral disease, lower LDH, higher hemoglobin, received more DOC cycles and had a longer treatment-free interval since last DOC (see Table). The median number of CAB cycles was higher in trials compared to SOC (5 vs 4, $p = 0.031$). Median OS was 13.6 vs 9.6 months for trial pts and SOC, respectively (HR 0.73, $p = 0.07$). PSA response ($\geq$ 50% decline) was 27 vs 11%, respectively ($p = 0.210$). However, after correction for prognostic factors, trial participation did not retain statistical significance (HR 0.94, $p = 0.73$), but longer period on ADT, lower LDH and absence of visceral metastases were significant for better OS. In addition, lower PSA and absence of symptoms had a trend for better OS.

Conclusions: The OS in the trial subgroup is in agreement with the OS of the TROPIC trial in a contemporary real world setting. However, the SOC pts had a trend for worse OS which may be explained by worse prognostic factors at CAB initiation. Accordingly, pts whose disease has progressed post-DOC should be carefully selected for treatment to ensure optimal outcomes.

Clinical trial identification: The CAPRI study is registered in the Dutch Trial Registry as NTR3591.

Legal entity responsible for the study: Institute for Medical Technology Assessment, Erasmus University Rotterdam.

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