



A multicentre, phase II randomised controlled trial evaluating docetaxel re-challenge versus cabazitaxel for the treatment of metastatic Castrate Refractory Prostate Cancer previously treated with docetaxel at inception of primary hormone therapy (EudraCT no 2012-003835-40)

Chief Investigator: Prof Nicholas James Sponsor: University of Birmingham

Sample Size: Total sample size of 138 (69 patients per arm)

CURRENTLY RECRUITING

STUDY SCHEMA

Patients treated with up-front docetaxel 75mg/m² as part of the STAMPEDE trial who have confirmed metastatic radiological or clinical relapse (or treated with same regimen but not part of STAMPEDE—must be discussed with trial office).



Phase II Randomisation

Patients will be stratified for prior exposure to abiraterone, enzalutamide (MDV3100) or other new generation hormone therapies (e.g. TAK700).



Cabazitaxel 25mg/m²
3 weekly plus prednisolone for up to
10 cycles



Docetaxel 75mg/m²
3 weekly plus prednisolone for up to
10 cycles



All patients will be assessed 3 weekly during treatment. Follow-up visits will occur at 3 monthly intervals for 2 years or until death (whichever is soonest).

Objectives: To assess the safety and levels of activity of cabazitaxel versus docetaxel re-challenge in patients previously exposed to combined docetaxel and androgen deprivation as first line treatment for advanced prostate cancer.

Selected Inclusion/Exclusion Criteria (but not exhaustive):

- ✓ Must have diagnosis of histologically proven prostate adenocarcinoma, that is castrate refractory.
- ✓ Must have been previously treated with up to 6 cycles of docetaxel as part of the STAMPEDE trial (no prior systemic therapy with chemotherapy drugs other than docetaxel).
- ✓ Must have confirmed biochemical, radiological or clinical progression.
- ✓ Must have metastatic disease.
- ✓ Must have WHO performance status grade 0 to 2.
- ✓ Must have adequate organ function (ANC >1.5 x10 9 /L; WBC >3.0 x10 9 /L; haemoglobin >100g/L; platelet count > 100 x10 9 /L.)
- **x** Patients with bilirubin \geq 1.0 xULN are <u>not eligible</u>.
- Patients with progressive disease whilst on primary docetaxel therapy are <u>not eligible</u>.
- * Patients <u>cannot</u> have metastatic brain disease or leptomeningeal disease.
- Patients with previous extensive palliative radiotherapy to bone marrow, e.g. hemibody radiotherapy are excluded.
- ➤ Patients with active grade ≥2 peripheral neuropathy (NCI CTC) are not eligible.
- * Patients with active infection requiring systemic antibiotic or anti-fungal medication are <u>not eligible</u>.

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