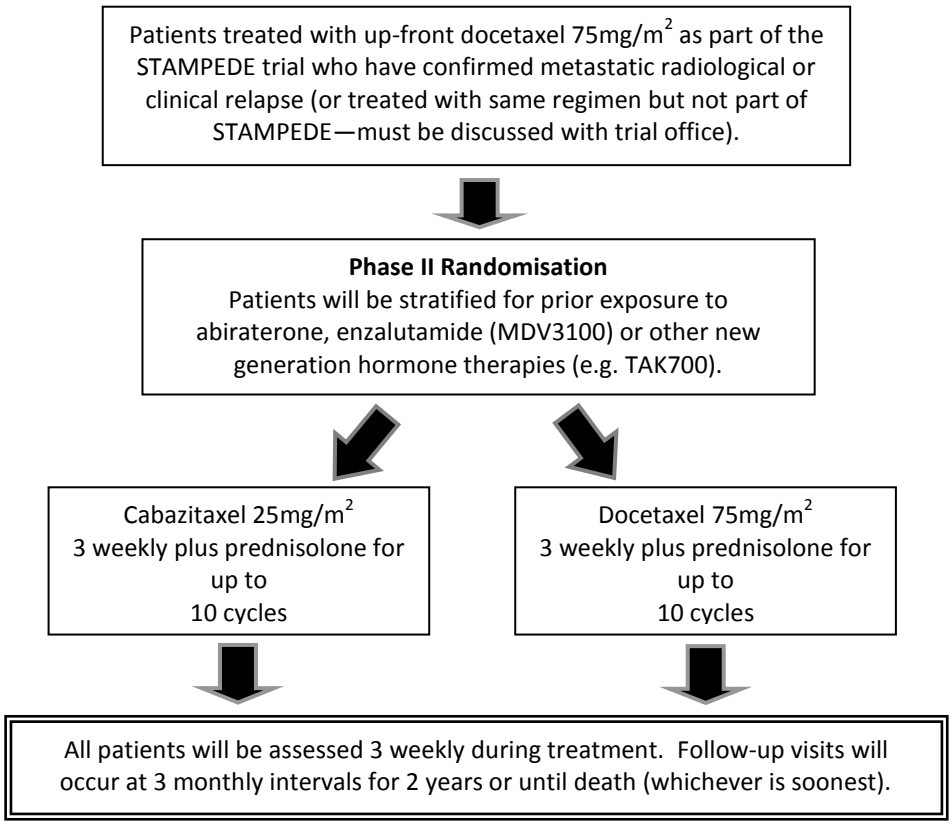
CANTATA

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



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.)
- × Patients with bilirubin ≥ 1.0 xULN are not eligible.
- × Patients with progressive disease whilst on primary docetaxel therapy are not eligible.
- × Patients cannot 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 not eligible.

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