

# A trial evaluating cabazitaxel versus docetaxel rechallenge for the treatment of metastatic castrate refractory prostate cancer, previously treated with docetaxel at inception of primary hormone therapy

<b>Submission date</b> 26/03/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/06/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/trials-search/a-trial-looking-at-cabazitaxel-for-prostate-cancer-that-has-started-to-get-worse-after-having-hormone-therapy-and-docetaxel-cantata>

## Contact information

### Type(s)

Scientific

### Contact name

Mr Nick Martin

### Contact details

Cancer Research UK Clinical Trials Unit  
Institute for Cancer Studies  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TT

-

CANTATA@trials.bham.ac.uk

## Additional identifiers

EudraCT/CTIS number

2012-003835-40

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

13741

## **Study information**

### **Scientific Title**

A multicentre, phase II randomised controlled trial evaluating cabazitaxel versus docetaxel rechallenge for the treatment of metastatic castrate refractory prostate cancer, previously treated with docetaxel at inception of primary hormone therapy

### **Acronym**

CANTATA

### **Study objectives**

This study compares the safety and levels of activity of cabazitaxel versus docetaxel rechallenge in patients with metastatic castrate refractory prostate cancer who have been previously exposed to combined docetaxel and androgen deprivation as first-line treatment for advanced prostate cancer.

The difference between treatment arms in terms of the number of patients who have a clinical event (clinical progression or death) will provide the evidence whether the levels of activity of cabazitaxel warrant further investigation in a phase III trial.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Liverpool Central - North West NRES Committee, 10/12/2012, ref: 12/NW/0792

### **Study design**

Randomised; Interventional; Design type: Treatment

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Prostate cancer

## **Interventions**

Patients will be randomised to one of the following two treatments (plus 10mg prednisolone daily in either regimen):

1. Cabazitaxel 25mg/m<sup>2</sup> 3 weekly plus prednisolone for up to 10 cycles
2. Docetaxel 75mg/m<sup>2</sup> 3 weekly plus prednisolone for up to 10 cycles

Follow Up Length: 24 month(s)

## **Intervention Type**

Drug

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

Cabazitaxel, docetaxel

## **Primary outcome measure**

Clinical progression-free survival (CPFS)

## **Secondary outcome measures**

No secondary outcome measures

## **Overall study start date**

07/03/2013

## **Completion date**

29/04/2016

# **Eligibility**

## **Key inclusion criteria**

1. Diagnosis of histologically proven prostate adenocarcinoma, that is castrate refractory
2. Previously treated with up to 6 cycles of Docetaxel at the same time (defined as commencing within 3 months) as instigation of primary hormone therapy.
3. Confirmed biochemical, radiological or clinical progression.
4. Metastatic disease
5. Male and female, aged 18 or over
6. WHO performance status grade 0 to 2
7. Adequate organ function as evidenced by:
  - 7.1. ANC >1.5 x10<sup>9</sup>/L
  - 7.2. WBC >3.0 x10<sup>9</sup>/L
  - 7.3. Haemoglobin >10g/dL

- 7.4. Platelet count  $> 100 \times 10^9/L$
- 7.5. Total bilirubin  $< 1.0 \times ULN$
- 7.6. AST/ ALT  $< 1.5 \times ULN$
- 7.7. GFR  $> 30 \text{ ml/min}$  (calculated by EDTA clearance, 24h urine collection, or Cockcroft-Gault)
- 8. Available for long-term follow up
- 9. Patients written informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

Planned Sample Size: 138; UK Sample Size: 138; Description: Target recruitment is 138 patients in total, with 69 patients per arm.

**Total final enrolment**

15

**Key exclusion criteria**

1. Prior systemic therapy with other chemotherapy drugs
2. Metastatic brain disease or leptomeningeal disease
3. Patients with bilirubin equal to or greater than  $1.0 \times ULN$
4. Previous extensive palliative radiotherapy to bone marrow, e.g. hemibody radiotherapy
5. Active grade  $\geq 2$  peripheral neuropathy (NCI CTC v 4)
6. Active infection requiring systemic antibiotic or antifungal medication
7. Patients with reproductive potential not implementing accepted and effective method of contraception

**Date of first enrolment**

07/03/2013

**Date of final enrolment**

12/01/2016

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**  
The Queen Elizabeth Hospital  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TH

## **Sponsor information**

**Organisation**  
University of Birmingham (UK)

**Sponsor details**  
Edgbaston  
Birmingham  
England  
United Kingdom  
B15 2TT

**Sponsor type**  
University/education

**Website**  
<http://www.birmingham.ac.uk/researchsupportgroup>

**ROR**  
<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Aventis Pharma Ltd T/A Sanofi-Aventis

**Funder Name**  
Cancer Research UK (UK)

**Alternative Name(s)**  
CR\_UK, Cancer Research UK - London, CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Results of this trial will be submitted for publication in a peer-reviewed journal. The manuscript will be prepared by the Trial Management Group (TMG) and authorship will be determined by mutual agreement.

**Intention to publish date**

31/12/2017

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publically available repository in 2017. Repository : European Medicines Agency (EMA)'s European Clinical Trial Database, EudraCT V10. URL : <http://eudract.ema.europa.eu>

**IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>			21/06/2019	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No