

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

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

Clinical Trials Information System (CTIS)

2012-003835-40

Protocol serial number

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

Study type(s)

Treatment

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/m² 3 weekly plus prednisolone for up to 10 cycles
2. Docetaxel 75mg/m² 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(s)

Clinical progression-free survival (CPFS)

Key secondary outcome(s)

No secondary outcome measures

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 $>1.5 \times 10^9/L$
 - 7.2. WBC $>3.0 \times 10^9/L$
 - 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 $>30ml/min$ (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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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 xULN
4. Previous extensive palliative radiotherapy to bone marrow, e.g. hemibody radiotherapy
5. Active grade ≥ 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**

United Kingdom

England

Study participating centre

The Queen Elizabeth Hospital

Edgbaston

Birmingham

United Kingdom

B15 2TH

Sponsor information**Organisation**

University of Birmingham (UK)

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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Basic results | | | 21/06/2019 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |