ISRCTN16465571 https://doi.org/10.1186/ISRCTN16465571

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	[_] Prospectively registered [_] Protocol
Registration date 26/03/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 21/06/2019	**Condition category** Cancer	[_] 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

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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 re-challenge 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/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 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 x109/L
7.2. WBC >3.0 x109/L
7.3. Haemoglobin >10g/dL

7.4. Platelet count > 100 x10^9L
7.5. Total bilirubin <1.0 xULN
7.6. AST/ ALT <1.5 xULN
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

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 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
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
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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?
Basic results			21/06/2019	No	No
HRA research summary			28/06/2023	No	No