

Treatment of locally advanced or metastatic transitional cell carcinoma with cabazitaxel

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|--|---|---|
| Submission date 01/11/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/02/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 07/03/2018 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-trial-cabazitaxel-for-transitional-cell-bladder-cancer-that-has-spread-cab-b1>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01668459

Secondary identifying numbers

RRK4368

Study information

Scientific Title

Cabazitaxel in platinum pre-treated patients with locally advanced or metastatic transitional cell carcinoma who developed disease progression within 12 months of platinum based chemotherapy

Acronym

Cab B1

Study objectives

The study aims to compare the overall response rate of cabazitaxel treatment versus best supportive care including single agent chemotherapy in patients with locally advanced or metastatic transitional cell carcinoma who developed disease progression within 12 months of platinum based chemotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Ethics Committee East Midlands - Leicester, 15/10/2012, ref: 12/EM/0363

Study design

Randomised open-label parallel-group study

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

Transitional cell carcinoma

Interventions

Cabazitaxel versus Best Supportive Care

Treatment duration: Up to 6 three weekly cycles of chemotherapy (18 weeks)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cabazitaxel

Primary outcome measure

Overall response rate. Time Frame: Change from baseline at Week 9 and Week 18

Secondary outcome measures

1. Overall survival: Defined as the time interval from the date of randomization to the date of death due to any cause. In absence of confirmation of death, survival time will be censored at the earlier of the last date the patient is known to be alive and the study cut-off date. Time Frame: From date of randomisation to the date of tumour progression or death (from any cause) (or survival at study cut-off date), whichever came first up to 12 months after the final patient has completed study treatment.
2. Quality of life, assessed using a validated instrument; the EuroQOL (EQ-5D). Time Frame: Change from baseline at Week 6, Week 12, Week 18, Week 21
3. Safety and tolerability: Dose delays and dose reductions, adverse events, laboratory safety data. Time Frame: From date of randomisation up to 30 days after final dose of study medication

Overall study start date

01/12/2012

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. Written informed consent
2. Age ≥ 18
3. Life expectancy ≥ 12 weeks
4. Patients with histology/cytology confirmed Transitional Cell Carcinoma (TCC) including mixed pathology with predominantly TCC, with locally advanced (T4b) or metastatic (lymph node or visceral) TCC arising from bladder or upper urinary tracts
5. Treated patients with incidental prostate cancer (pT2, Gleason ≤ 6) and PSA (Prostate Specific Antigen) ≤ 0.5 ng/mL are eligible
6. Measurable disease as per RECIST Criteria 1.1
7. ECOG Performance Status 0-1
8. Previously received first line platinum based treatment
9. Recurrence within 12 months (by RECIST criteria version 1.1) from last cycle of chemotherapy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

96 (25 patients will be initially recruited and after interim analysis, a further 71 patients may be recruited)

Key exclusion criteria

1. Previous therapy with a taxane
2. Pure non TCC histologies
3. Grade II or more peripheral neuropathy
4. Prior surgery, radiation, chemotherapy, or other anti-cancer therapy within 4 weeks prior to enrolment in the study
5. Uncontrolled severe illness or medical condition (including uncontrolled diabetes mellitus)
6. Inadequate organ and bone marrow function as evidenced by:
 - 6.1. Hemoglobin < 9.0 g/dL
 - 6.2. Absolute neutrophil count < $1.5 \times 10^9/L$
 - 6.3. Platelet count < $100 \times 10^9/L$
 - 6.4. AST/SGOT and/or ALT/SGPT > $2.5 \times ULN$
 - 6.5. Total bilirubin > $1.0 \times ULN$
 - 6.6. Serum creatinine > $1.5 \times ULN$. If creatinine $1.0 - 1.5 \times ULN$, creatinine clearance will be calculated according to CKD-EPI formula and patients with creatinine clearance ≤ 30 mL/min should be excluded
7. Symptomatic brain metastases or leptomeningeal disease (CT or MRI scan of the brain required only in case of clinical suspicion of central nervous system involvement)
8. History of another neoplasm except non-metastatic melanoma skin cancers, carcinoma in situ of the cervix, or cancer cured by surgery, small field radiation or chemotherapy < 5 years prior to randomization
9. History of inflammatory bowel disease, significant bowel obstruction
10. History of hypersensitivity to platinum, gemcitabine, taxanes, Polysorbate-80, or to compounds with similar chemical structures
11. Any of the following events within 6 months prior to randomization: myocardial infarction, severe/unstable angina, coronary/peripheral artery bypass graft surgery, clinically symptomatic and uncontrolled cardiovascular disease, or clinically significant arrhythmias (grade 3-4)
12. Concurrent treatment with strong inhibitors of cytochrome P450 3A4 or patients planning to receive these treatments. For patients who were receiving treatment with such agents, a one-week washout period is required prior to randomization
13. Women who are breastfeeding and women of child bearing potential (not postmenopausal (12 months of amenorrhea) or surgically sterile (absence of ovaries and/or uterus)) unless in agreement to use an adequate method of contraception during the treatment period and for 6 months after the last dose of the study drug. Men unless in agreement that they will use effective contraception (and condom to protect against exposure to seminal liquid) whilst participating in the trial and for 6 months after the last dose of study medication

Date of first enrolment

01/12/2012

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Queen Elizabeth Hospital Birmingham

Edgbaston

United Kingdom

B15 2TH

Sponsor information

Organisation

University Hospitals Birmingham NHS Foundation Trust (UK)

Sponsor details

c/o Dr Chris Counsell

Queen Elizabeth Hospital Birmingham

Edgbaston

England

United Kingdom

B15 2TH

Sponsor type

Hospital/treatment centre

Website

<http://www.uhb.nhs.uk/>

ROR

<https://ror.org/014ja3n03>

Funder(s)

Funder type

Industry

Funder Name

Sanofi Aventis (France)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 20/05/2017 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |