ISRCTN76947550 https://doi.org/10.1186/ISRCTN76947550

Treatment of locally advanced or metastatic transitional cell carcinoma with cabazitaxel

Submission date 01/11/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/02/2013	**Overall study status** Completed	
Last Edited 07/03/2018	**Condition category** Cancer	

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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01668459

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 x 109/L
6.3. Platelet count < 100 x 109/L
6.4. AST/SGOT and/or ALT/SGPT > 2.5 x ULN
6.5. Total bilirubin > 1.0 x ULN
6.6. Serum creatinine > 1.5 x ULN. If creatinine 1.0 - 1.5 x 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
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital Birmingham
Edgbaston

United Kingdom
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Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust (UK)

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Industry

Funder Name
Sanofi Aventis (France)

Results and Publications

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