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Study of preoperative everolimus in metastatic renal cell cancer

Submission date 17/08/2011	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 17/08/2011	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 04/12/2017	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-using-everolimus-advanced-kidney-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2009-013381-54

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10710

Study information

Scientific Title
A phase II study of preoperative everolimus in metastatic renal cell cancer

Acronym
E-PREDICT

Study objectives
Participants will be treated with everolimus 10mg orally daily for 6 weeks with repeat CT scanning, functional imaging and CTC/CEC sampling after 6 weeks. Cytoreductive nephrectomy will be carried out 1 week after stopping everolimus and molecular analyses carried out on the nephrectomy specimen. Everolimus will be continued post-operatively in all patients that derived benefit from pre-operative treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Royal Marsden Research Ethics Committee-now the London-Chelsea REC, First MREC approval date 16/11/2009, ref: 09/h0801/96

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Renal Cancer; Disease: Kidney

Interventions
The sample size calculation is based on a Simon optimal two-stage design using a type I error level of 5% and power of 80%. We assume the treatment to be acceptable if less than 1% (P1=0. 99) of patients experience non-haematological grade 4 toxicity or death due to the drug. If more than 10% (P0=0.90) of patients experience grade 4 non-haematological toxicity or death, the treatment is unacceptable.

Everolimus to be taken orally 10mg per day for 6 weeks prior to nephrectomy and then subsequent to nephrectomy until disease progression and following progression, if deriving clinical benefit.

Follow Up Length: 12 month(s); Study Entry : Registration only

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Everolimus

Primary outcome measure
Primary Outcome; Timepoint(s): safety of pre-operative and post-operative everolimus therapy in 19 evaluable patients

Secondary outcome measures
1. Efficacy [response rate (RR), progression-free survival (PFS), overall survival (OS)]
2. Toxicity (CTC)
3. Biomarkers (exploratory qualitative)

Overall study start date
18/01/2010

Completion date
18/06/2012

Eligibility

Key inclusion criteria
1. Histologically confirmed metastatic renal cell carcinoma
2. At least one site of disease outside the kidney measurable per Response Evaluation Criteria In Solid Tumors (RECIST)
3. Scheduled to undergo nephrectomy as part of treatment plan
4. No prior systemic therapy for renal cell carcinoma
5. Male or female, 18 years of age or older
6. Life expectancy of 12 weeks or greater
7. Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
8. Serum aspartate transaminase (AST) serum alanine transaminase (ALT) = 2.5 x upper limit of normal (ULN), or AST and ALT = 5 x ULN if liver function abnormalities are due to underlying malignancy
9. Total serum bilirubin = 1.5 x ULN
10.Serum creatinine = 1.5 x ULN
11. Absolute neutrophil count (ANC) = 1.5 x109/L
12. Platelets = 100 x109/L
13. Haemoglobin = 9.0 g/dL
14. Prothrombin time (PT) = 1.5 x ULN

15. Signed and dated informed consent document indicating that the patient (or legally acceptable representative) has been informed of all pertinent aspects of the trial prior to enrolment
16. Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures; Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Intracranial disease, unless there has been radiological evidence of stable intracranial disease > 6 months. In the case of a solitary brain metastasis, evidence of a disease-free interval of at least 3 months post surgery. All patients previously treated for brain metastases must be stable off corticosteroid therapy for at least 28 days
2. Need for nephrectomy to relieve symptoms relating to the primary tumour or for emergency nephrectomy
3. Diagnosis of any second malignancy within the last 5 years, except for adequately treated basal cell carcinoma, squamous cell skin cancer, or in situ cervical cancer
4. Known human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) related illness
5. Pregnancy or breastfeeding. Female patients must be surgically sterile or be postmenopausal, or must agree to use effective contraception during the period of therapy. All female patients with reproductive potential must have a negative pregnancy test (serum or urine) prior to enrolment. Male patients must be surgically sterile or must agree to use effective contraception during the period of therapy
6. Current signs or symptoms of severe progressive or uncontrolled hepatic, haematologic, gastrointestinal, endocrine, pulmonary or cardiac disease other than directly related to renal cell cancer (RCC)

Date of first enrolment
18/01/2010

Date of final enrolment
18/06/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Marsden Hospital
London
United Kingdom
SW3 6JJ

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust (UK)

Sponsor details
c/o Jane Lawrence
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Sponsor type
Research organisation

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Novartis Pharma AG (UK)

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