ISRCTN57274668 https://doi.org/10.1186/ISRCTN57274668

Biomarkers in patients with renal cell carcinoma

Submission date 19/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 07/02/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/09/2021	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-biomarkers-people-kidney-cancer

Contact information

Type(s)
Scientific

Contact name
Prof Duncan Jodrell

Contact details
Oncology Centre, Box 193
Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BioM1

Study information

Scientific Title

Renal cancer biomarkers of angiogenesis in renal cell carcinoma (RCC): a multicentre, prospective, non-randomised, observational study

Acronym
BioM1

Study objectives
The principal objective is to establish the intra-individual and inter-individual variability in baseline reading of candidate angiogenic biomarkers in patients with clear cell renal cell carcinoma (RCC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 1 REC pending as of 22/11/2010, ref: 10/H0304/096

Study design
Multicentre prospective non-randomised observational study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Renal cell carcinoma

Interventions
Patients will provide, on visit one (day one), a blood sample and urine sample for testing of plasma biomarkers, serum chemistry, haematology and metabolite analysis. These samples will again be taken on visit two (between days 2 and 21).

Blood samples will be analysed at the Patterson Institute in Manchester, tests include (but are not limited to) VEGF, PIGF, sVEGFR-2, KGF, IL-8, FGF-ß, HGF, PDGF-BB, Ang1, Ang2, Tie2, SDF-1a, M65, M30. Plasma and urine samples will be analysed for various metabolites, including amino acids, sugars, oxoacids and osmolytes.

The trial duration for the patient will be 28 days maximum.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The principal objective is to establish the intra-individual and inter-individual variability in baseline reading of candidate angiogenic biomarkers in patients with clear cell RCC. Patient samples taken on day one and anytime from day 2 - 21.

Secondary outcome measures
The study endpoint is to measure the baseline readings of angiogenic biomarkers in patients with clear cell RCC. Patient samples taken on day one and anytime from day 2 - 21.

Overall study start date
04/01/2011

Completion date
31/01/2012

Eligibility

Key inclusion criteria
1. Newly diagnosed histologically or cytologically confirmed renal cell carcinoma with a clear cell component; patients who have a radiological diagnosis of probable renal cell carcinoma can be included whilst still awaiting biopsy or surgery and once confirmed to have clear cell renal cell carcinoma, they will be included in the study. If their histology confirms a non-clear cell renal cell carcinoma, they will be replaced.
2. Metastatic renal cell carcinoma with a clear cell component with previous nephrectomy but with no previous history of use of systemic therapy with the exception of immunotherapy, provera and bisphosphonates. Prior palliative radiotherapy is permitted.
3. Ability and willingness to provide written informed consent
4. Ability and willingness to co-operate with study procedures, including blood and urine sampling
5. Aged greater than or equal to 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

80

Key exclusion criteria
1. Previous history of cancer other than RCC, autoimmune diseases or known active infection
2. Previous history of use of systemic therapy for treatment of renal cell carcinoma other than immunotherapy, provera and bisphosphonates. Prior palliative radiotherapy is not an exclusion criterion.
3. Patients who commence therapy in between study visits (sample collection); although if the first sample is already collected before starting treatment, then that sample will be processed and the second sample will not be collected
4. Known human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS)-related illness, HBV and HCV

Date of first enrolment
04/01/2011

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
Trust R&D Dept, Box 277
Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

ROR
https://ror.org/04v54gj93

Organisation
University of Cambridge (UK)

Sponsor details
Research Office
School of Clinical Medicine
Addenbrooke's Hospital, Box 111
Hills Road
Cambridge
England
United Kingdom
CB2 0SP
+44 (0)1223 333543
croenquiries@admin.cam.ac.uk

Sponsor type
University/education

Website
http://www.cam.ac.uk/

Funder(s)

Funder type
Government

Funder Name
Cambridge University Hospitals NHS Foundation Trust (UK) - Phase I Cancer Trials Team

Funder Name
Patterson Institute for Cancer Research (UK)

Funder Name
St James University Hospital (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