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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Other

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, PlGF, 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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Organisation
University of Cambridge (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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes