

# Biomarkers in patients with renal cell carcinoma

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>19/11/2010   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>07/02/2011 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>09/09/2021       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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

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### Contact details

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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

**Primary study design**

Observational

**Study design**

Multicentre prospective non-randomised observational study

**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, PIGF, sVEGFR-2, KGF, IL-8, FGF- $\beta$ , 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