

18F-labelled sodium fluoride positron emission tomography - computed tomography (PET-CT) for renal cell carcinoma (RCC)

Submission date 23/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English Summary

Background and study aims

Every year in the UK 6000 patients are diagnosed with renal cell carcinoma (kidney cancer). Many patients will initially present with advanced or unresectable disease (a tumor that cannot be completely removed by surgery). 30% of patients who undergo a nephrectomy (removal of a kidney) will relapse. Metastatic clear cell renal carcinoma is a type of kidney cancer that is generally resistant to chemotherapy. Metastases (tumors formed by cells that have spread) are a strong predictor of poor survival in patients with renal carcinoma. Only 0-2% of patients with advanced metastatic disease survive longer than five years, and early diagnosis and management has the potential to improve patient survival. If there are symptoms suggestive of bone metastases, then a bone scan (bone scintigraphy) is considered. Bone metastases from renal carcinoma can be poorly visualised or even missed on bone scintigraphy. In this study we will be looking at the use of a type of scan called 18F-FDG positron emission tomography (PET) for detecting bone metastases in renal cell carcinoma patients, as this type of scan has a higher sensitivity of detection.

Who can participate?

Male or female patients, 18 years of age or older, diagnosed with renal cell carcinoma.

What does the study involve?

Patients will undergo one bone scan (4 hours) and one PET/CT scan (2 hours). A bone scan is usually standard practice should a patient have signs/symptoms of possible bone metastases. Patients will receive a follow-up telephone call lasting about 15 minutes within 2 weeks of the last imaging scan. Continued follow-up will be as per standard practice.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Addenbrookes Hospital, Cambridge (UK).

When is the study starting and how long is it expected to run for?
The study will run from March 2011 to January 2012.

Who is funding the study?
Addenbrookes Hospital, Cambridge (UK).

Who is the main contact?
Dr Ferdia Gallagher
Addenbrookes Hospital, Cambridge (UK).

Contact information

Type(s)
Scientific

Contact name
Dr Ferdia Gallagher

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.2

Study information

Scientific Title

A pilot study investigating the sensitivity of 18F-labelled sodium fluoride positron emission tomography - computed tomography (PET-CT) for detecting skeletal metastases in renal cell carcinoma compared to planar bone scintigraphy and multidetector computed tomography (CT)

Study hypothesis

The aim of this study is to determine if 18F-labelled sodium fluoride (Na18F) positron emission tomography - computed tomography (PET-CT) is more sensitive at detecting bone metastases in renal cell carcinoma than conventional techniques i.e. planar bone scintigraphy and computed tomography (CT). Number, site, and extent of metastases will be evaluated.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 23/08/2011:

Submitted to Brighton and Sussex REC as Cambridgeshire 2 REC did not have slots available.

Approved on 12/07/2011 (ref: 11/LO/0399)

Study design

Single centre non-randomised non-controlled pilot feasibility study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

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

Condition

Renal cell carcinoma

Interventions

Patients will undergo one bone scan (4 hours) and one PET/CT (2 hours) scan as part of the trial. A bone scan is usually standard practice should a patient have signs/symptoms of possible bone metastases. PET/CT scan will be taken following consent and before starting treatment, if a bone scan has not previously been undertaken at Addenbrooke's Hospital, this will be completed within 28 days of the PET/CT scan. Patients will be on trial for approximately 2 months after giving consent. Patients will receive a follow up telephone call lasting approx 15 minutes within 2 weeks of the last imaging scan. Continued follow up will be as per standard practice.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Number of metastases detected with Na¹⁸F-PET-CT, bone scintigraphy and multidetector CT alone

Scans will be taken within 28 days of giving consent. At the end of the study or at withdrawal for other reason, correlation of PET findings with clinical outcome (overall survival and, where available, progression-free survival and outcome defined by imaging on RECIST criteria) will be performed.

Secondary outcome measures

1. Site and extent of metastases detected with Na¹⁸F-PET-CT, bone scintigraphy and multidetector CT
2. Response to treatment correlation to the appearance of metastases detected with Na¹⁸F-PET and CT
3. Arterial calcium assessment on the CT; correlation with the Na¹⁸F-PET uptake

Scans will be taken within 28 days of giving consent. At the end of the study or at withdrawal for other reason, correlation of PET findings with clinical outcome (overall survival and, where available, progression-free survival and outcome defined by imaging on RECIST criteria) will be performed.

Overall study start date

01/03/2011

Overall study end date

31/01/2012

Eligibility

Participant inclusion criteria

1. Male or female, 18 years of age or older with no upper age limit
2. Must be able to provide a written informed consent according to International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use /Good Clinical Practice (ICH/GCP), national and local regulations
3. All female patients with reproductive potential must have a negative pregnancy test (serum or urine) prior to enrolment
4. Treatment-naïve patients in the first instance. If at 6 months, insufficient numbers (less than 5) can be recruited in the time period between diagnosis and treatment, then patients that have been treated will also be recruited after the first cycle of chemotherapy.
5. Life expectancy of 12 weeks or greater
6. Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2
7. Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

10 - 20 participants

Participant exclusion criteria

1. Diagnosis of any other malignancy within the last 5 years, except for adequately treated basal cell carcinoma, squamous cell skin cancer, or in situ cervical cancer
2. Allergy to methylene diphosphonate used in bone scintigraphy
3. Any metabolic disorder that involves the skeletal system
4. Known human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS)-related illness
5. Pregnancy or breastfeeding. All female patients with reproductive potential must have a negative pregnancy test (serum or urine) prior to enrolment.
6. Other severe acute or chronic medical or psychiatric condition, or laboratory abnormality that may increase the risk associated with study participation or study drug administration, or in the judgment of the investigator would make it undesirable for the patient to enter the trial
7. Not suitable to undergo a PET study, e.g., extreme obesity: greater than 226 kg

Recruitment start date

01/03/2011

Recruitment end date

31/01/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Department of Radiology**

Cambridge

United Kingdom

CB2 0QQ

Sponsor information**Organisation**

Cambridge University Hospitals NHS Foundation Trust and University of Cambridge (UK) - Joint Sponsorship

Sponsor details

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

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Addenbrooke's Hospital (UK) - Radiology Department

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2015	16/01/2019	Yes	No
HRA research summary			28/06/2023	No	No