ISRCTN66828876 https://doi.org/10.1186/ISRCTN66828876

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

Submission date	Recruitment status	[_] Prospectively registered
23/12/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/01/2019	Cancer	

Plain English summary of protocol

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

Contact details
Department of Radiology
Box 218 Level 5
Addenbrookes Hospital
Cambridge
United Kingdom
CB2 0QQ

Additional identifiers

Protocol serial number
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 objectives
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

Study type(s)
Screening

Health condition(s) or problem(s) studied
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(s)
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.

Key secondary outcome(s))
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.

Completion date
31/01/2012

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key 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

Date of first enrolment
01/03/2011

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
United Kingdom

England

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

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Addenbrooke's Hospital (UK) - Radiology Department

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?
Results article	results	01/10/2015	16/01/2019	Yes	No
HRA research summary			28/06/2023	No	No