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18-Fluorothymidine positron emission tomography (18-FLT PET/CT) to assess tumour proliferation during radical radiotherapy

Submission date 27/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/07/2010	**Overall study status** Completed	
Last Edited 22/09/2017	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-using-PET-CT-scan-look-at-changes-in-cancer-cells-during-radiotherapy

Contact information

Type(s)
Scientific

Contact name
Dr Anastasia Chalkidou

Contact details
The Rayne Institute
4th Floor Lambeth Wing
St Thomas Hospital
London
United Kingdom
SE1 7EH
-
Anastasia.Chalkidou@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8495

Study information

Scientific Title
Research study of 18-FLT (18F-3'-fluoro-3-deoxy-L-thymidine) positron emission tomography (PET/CT) sequential imaging to quantify tumour proliferation during radical radiotherapy in patients with non-small cell lung cancers and head and neck cancers

Study objectives
Despite impressive advances in radiotherapy over recent years many tumours are still not cured by radical doses of radiation, partly because tumours respond to radiotherapy by growing more rapidly ('accelerated repopulation'). This makes treatment rather like running down an upward escalator. In this study an imaging technique is investigated that might help us identify whether accelerated repopulation is taking place in individual patients, when it begins, how fast it is progressing, and where in the tumour it is occurring. This could help to individualise patient treatments, both by modifying treatment schedules to minimise repopulation and by selectively raising doses delivered to rapidly repopulating tumour regions - with the aim of curing more patients using radiotherapy.

Twenty patients with either lung cancer or head and neck cancer who are being treated using radiotherapy will undergo a series of 6 positron emission tomography (PET) scans, imaging a novel thymidine-based tracer called fluoro-L-thymidine (FLT). FLT uptake measured in PET images has been found to correlate with levels of a biomarker of proliferation measured in surgical specimens, and is increasingly being investigated as a measure of tumour proliferation in cancer patients. To make the best use of the PET imaging data a set of technical processes will be established so that FLT tracer uptake per voxel can be measured accurately. These complex data will relate to the same parts of the tumour and therefore can be compared consistently across a series of scans. The sequences of PET images collected in the study will be comprehensively analysed exploring the time-course and spatial maps of tumour proliferation.

These data will enable the comparison of the effect of radiotherapy on DNA damage and provide proof of principle data on whether FLT relates to this. These data may then show how radiotherapy can be modified to minimise the scope for accelerated proliferation and target rapidly proliferating tumour regions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Thomas REC, 12/04/2010, (ref: 10/H0802/2

Study design
Single-centre non-randomised interventional trial

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Head and Neck Cancer, Lung Cancer; Disease: non small cell lung cancer

Interventions
1. Arterial line: Arterial line placed in the radial artery by experienced Intensive Care Unit physicians. Blood tests taken from this arterial line.
2. Biopsy material: Ultrasound guided fine needle aspiration for head and neck cancer patients once during radiotherapy.
3. PET/CT scan with new tracer: PET/CT scan with FLT. From injection to end of scanning is about 75 minutes. Undertaken by fully trained PET centre staff.
4. Radiotherapy mask: Radiotherapy mask will be used in head and neck patients to position the patient for the scanning.
5. Venepuncture: Blood test during each PET scan.

Follow-up length: 3 months
Study entry: registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Stability of tumour FLT spatial uptake pattern throughout treatment, measured during treatment and 3 months afterwards.

Secondary outcome measures
1. Average time-course of overall tumour FLT uptake
2. Patient-to-patient differences in FLT uptake time-course
3. Characterisation of typical spatial pattern of tumour FLT uptake
4. Patient-to-patient variability in tumour FLT spatial uptake patterns
5. Relationships between CK-18Asp396 levels in blood and changes in tumour FLT uptake between scans
6. Comparison of FLT kinetics with SUV values

All the secondary outcomes will be measured at baseline, during radiotherapy and at 3 months follow up.

Overall study start date
17/06/2010

Completion date
31/01/2012

Eligibility

Key inclusion criteria
1. About to undergo radical radiotherapy for one of the following:
1.1. Non-small cell lung cancer with staging between I - III and either the primary tumour or an involved lymph node being greater than 3 cm in maximum dimension
1.2. Squamous cell carcinoma of the head and neck region with staging between II - IVA and either the primary tumour or an involved lymph node being greater than 3 cm in maximum dimension
2. Over 18 years of age, either sex
3. Able to understand consent form
4. Fit for extra incovenience of longer stays in hospital on days of scans
5. Receiving chemotherapy concurrently with radiotherapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 20; UK sample size: 20

Key exclusion criteria
1. Patient unfit to attend extra scanning visits
2. Tumour criteria not met
3. Clotting disorder for head and neck group
4. Severe claustrophobia or inability to tolerate PET/CT
5. Unable to provide written consent
6. Pregnant or breastfeeding women
7. Subjects taking nucleoside analog medications such as those used as antiretroviral agents

Date of first enrolment
17/06/2010

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Rayne Institute
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St. Thomas' NHS Foundation Trust (UK)

Sponsor details
2nd Floor, Conybeare House
Great Maze Pond
London
England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/04/2014		Yes	No