ISRCTN34165059 https://doi.org/10.1186/ISRCTN34165059

Role of MRI and PET CT for radiotherapy planning for head and neck cancer

Submission date 23/01/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 02/02/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 07/03/2023	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Radiotherapy is a treatment involving the use of high-energy radiation. It is commonly used to treat advanced cancers of the head and neck, aiming to cure while preserving patients' quality of life including their ability to speak and swallow. In order to reduce the potentially major side effects of treatment, it is essential that the highest doses of radiotherapy are targeted to the main bulk of the tumour. At present a computerized tomography (CT) scan is used by the cancer specialist to identify the tumour for planning the radiotherapy treatment. We know that other types of scan including magnetic resonance imaging (MRI) and positron emission tomography (PET) scans are better than CT scans at showing areas invaded by the cancer. However, radiotherapy cannot be directly planned on these types of scans. The aim of this study is to explore whether PET and MRI scans can be combined with CT scans to more accurately identify the tumour target. In addition, this study will explore whether PETCT and MRI scans may be used to adjust radiotherapy to how well a tumour is responding during a course of radiotherapy.

Who can participate?
Patients aged 18 or over with cancers of the head and neck undergoing a course of radiotherapy.

What does the study involve?
All patients within the study will undergo a PETCT and an MRI scan prior to starting treatment as part of the study. A subgroup of patients will undergo additional imaging at two timepoints during the course of their radiotherapy.

What are the possible benefits and risks of participating?
If the radiotherapy planning process can be improved in these ways, we hope future patients will benefit by more chance of cure with a reduction in the side effects of treatment. The participants' standard treatment will not be affected by their participation in the study.

Where is the study run from?
St James's University Hospital (UK).

When is the study starting and how long is it expected to run for?
From July 2011 to May 2013.

Who is funding the study?
Leeds Teaching Hospitals Charitable Foundation (UK).

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CO10/9645

Study information

Scientific Title
Assessment of the use of co-registered 18-fluorodeoxyglucose-PET-CT and MRI for radiotherapy planning in locally advanced head and neck squamous cell carcinoma: a pilot study

Study objectives
An imaging study, with no change made to patients' treatment:
1. To explore whether PET and MRI scans can be combined with CT scans to more accurately identify the tumour target for radiotherapy planning
2. To explore whether PET-CT and MRI scans may be used to detect alterations in the tumour during a course of radiotherapy, to allow the future design of studies to look at adapting treatment according to tumour response

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service, Yorkshire and Humber (UK), 25/07/2011, reference: 11/YH/0212

Study design
Single-centre pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Radiotherapy for head and neck cancer

Interventions
1. Patients will have an MRI scan and an 18-fluorodeoxyglucose (18FDG)-PET-CT scan in a radiotherapy mask before the start of radiotherapy treatment
2. A subset of patients within the study will have repeat MRI and 18-FDG-PET-CT scans after 2 weeks and 4 weeks of radiotherapy treatment

Intervention Type

Procedure/Surgery

Primary outcome measure
Accuracy of imaging with a 18FDG-PET-CT and MRI for identification of head and neck tumours for radiotherapy planning, assessed with intraobserver and interobserver comparison of delineation of tumour target by radiologists and radiation oncologists using PET, MRI and CT imaging; analysis will be done when recruitment is complete

Secondary outcome measures
1. To determine whether CT scan routinely used to plan radiotherapy can be accurately merged with an MRI scan
2. To determine the feasibility of performing MRI and PET-CT imaging during a course of radiotherapy
3. To identify the most useful timepoints for imaging during radiotherapy to track tumour changes
4. To determine whether changes on MRI and PET-CT taken during radiotherapy could be used to improve the radiotherapy plan during treatment

These endpoints will be evaluated with quantitative contour comparison tools. Analysis will be done when recruitment is complete.

Overall study start date
25/07/2011

Completion date
07/05/2013

Eligibility

Key inclusion criteria
1. Age ≥18 years old
2. WHO performance status 0-2
3. Histologically proven squamous cell carcinoma of the head and neck region
4. Clinical decision made to proceed with a course of radiotherapy of curative intent of 66-70Gy in 33-35 fractions over 6.5–7 weeks with or without concurrent chemotherapy
5. Measurable primary tumour and/or locoregional metastatic lymph nodes on preradiotherapy imaging
6. Able to provide written informed consent
7. Able to lie flat for 1 hour
8. Female patients of childbearing potential must agree to use effective contraception, be surgically sterile, or be postmenopausal

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15 patients

Key exclusion criteria
1. Hypersensitivity to fluorine-18 FDG
2. Hypersensitivity to iodinated contrast media or gadolinium
3. Poorly controlled diabetes
4. Acute renal failure or moderate renal impairment (estimated glomerular filtration rate < 30 mL /min)
5. Contraindication to MRI imaging, including cardiac pacemaker or presence of MRI incompatible metalwork
6. Claustrophobia precluding MRI imaging
7. Uncontrolled pain
8. Urinary incontinence
9. Female patients must not be pregnant
10. Breastfeeding
11. Serious psychiatric comorbidity

Date of first enrolment
25/07/2011

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James's University Hospital
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

Sponsor details
Research and Development
34 Hyde Terrace
Leeds
England
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LS2 9LN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Charity

Funder Name
Leeds Teaching Hospitals Charitable Foundation

Results and Publications

Publication and dissemination plan
Aim to publish outcomes in a peer reviewed journal in 2015/6

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/03/2015		Yes	No
Results article	results	04/11/2015		Yes	No
Results article		08/07/2016	07/03/2023	Yes	No