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Variation of radiotherapy target volume definition, dose to organs at risk (OAR) and clinical target volumes using anatomic (CT) versus combined anatomic and molecular imaging (PET-CT): Intensity Modulated Radiotherapy delivered using a Tomotherapy Hi Art machine

Submission date 29/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/04/2010	**Overall study status** Completed	
Last Edited 12/12/2017	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-see-pet-scans-help-improve-radiotherapy-treatment-planning-oropharyngeal-cancer-vortigern

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7341

Study information

Scientific Title
Variation of radiotherapy target volume definition, dose to organs at risk (OAR) and clinical target volumes using anatomic (CT) versus combined anatomic and molecular imaging (PET-CT): Intensity Modulated Radiotherapy delivered using a Tomotherapy Hi Art machine

Acronym
VortigERn

Study objectives
30 patients with head and neck cancer who are being treated with intensity modulated radiotherapy (IMRT) will be recruited in the study. Patients willing to give consent to participate will be asked to have a contrast enhanced positron emission tomography - computed tomography (PET-CT) scan. The CT scan data will then be used to define the CTV1 and CTV2 for IMRT treatment (as per agreed protocol) as standard. A computer based IMRT plan will be generated for optimal treatment of the patient using the CT information only. The patient will be treated on the basis of this.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved on the 20/10/2008 (ref: 08/H0907/127)

Study design
Non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

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: All Cancers/Misc Sites; Disease: Unknown Primary Site

Interventions
Standard pre-radiotherapy planning imaging is with a contrast enhanced CT scan. In the study all patients were required to have a 18 FDG PET-CT scan in the treatment position.

Study entry: registration only

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To explore if the FDG PET CT based radiotherapy target volumes are different to that of CT scan

Secondary outcome measures
Feasibility of dose escalation in tumour volumes in oropharyngeal SCC.

Overall study start date
01/05/2009

Completion date
02/03/2010

Eligibility

Key inclusion criteria
1. Tumours of oropharynx area in the head and neck
2. Have involved or uninvolved neck nodes
3. Being treated with tomotherapy IMRT
4. Either sex

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
Planned Sample Size: 30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2009

Date of final enrolment
02/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Centre for Cancer Care
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle Hospitals NHS Foundation Trust (UK)

Sponsor details
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
United Kingdom
NE7 7DN

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Research organisation

Funder Name
Royal College of Radiologists (UK)

Alternative Name(s)
The Royal College of Radiologists, RCR

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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	01/12/2012		Yes	No