ISRCTN33175361 https://doi.org/10.1186/ISRCTN33175361

# 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

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