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Evaluation of hypoxia using genetic and imaging biomarker in head and neck squamous cell carcinoma

Submission date 10/10/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/10/2012	**Overall study status** Completed	
Last Edited 16/01/2017	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-new-way-work-out-oxygen-levels-throat-cancer-bohemian-study

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
13125

Study information

Scientific Title
Biomarkers of hypoxia evaluation with molecular and 64copper (II) diacetylbis (N4) methylthiosemicarbazone (CuATSM) positron emission tomography/computed tomography (PET /CT) imaging techniques in head and neck squamous cell carcinomas (BoHEMIaN study)

Acronym
BoHEMIaN

Study objectives
Hypoxia has long been identified as an important prognostic factor in head and neck cancer. It is associated with poorer loco-regional control and survival in patients treated with radiotherapy. Despite many interventional studies targeting hypoxia, the inability to prospectively identify high risk patients continues to make efforts to overcome hypoxia inefficient, as well as exposing low risk patients to unnecessary treatment toxicity. Current methods being investigated to identify hypoxia from an early stage include the use of molecular and imaging biomarkers of hypoxia. This study will look at exisitng and novel molecular biomarkers from diagnostic biopsy samples and correlate these with the Cu-ATSM PET/CT derived hypoxia score. The aim is to identify a hypoxic molecular signature which will allow the selection of patients who will benefit from hypoxia imaging, with subsequent tailoring of their treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London City and East NRES, 02/08/2012, ref: 12/LO/1123

Study design
Non-randomised interventional trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Head and neck cancer

Interventions
Tissue samples will be obtained from the Head and Neck Tissue and Data Bank. Immunohistochemistry, expression profiling and miRNA screening to investigate markers of hypoxia will be performed. Copper-ATSM PET images will be interpreted using tumour/muscle ratio and standardised uptake values, and patients will be grouped into tumours with a high or low hypoxia index. Previously defined gene/miRNA expression signatures will be tested for association with the Copper-ATSM derived hypoxia score, immunohistochemical markers and 3 month treatment response. Supervised analyses for discovery of differential gene expression and miRNA expression between high/low hypoxia index tumours will be performed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Characterisation and correlation of molecular and imaging biomarkers of hypoxia

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Patients with stage III-IV histologically proven HPV negative oropharyngeal squamous cell carcinoma to be treated with radical concomitant chemotherapy and radiotherapy
2. Patients have consented to their original biospy being stored in the tissue bank at GSTFT
3. Age > 18 years
4. ECOG Performance Status </= 2
5. Life expectancy > 12 weeks
6. Adequate organ function and absence of other major concomitant illness, allowing the patient to tolerate the delivery of the radiotracer
7. Patients must be able to provide written and voluntary informed consent
8. All women of childbearing age must have a negative serum or urine pregnancy test documented within 72 hours prior to study enrollment
9. Male and female participants

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with impaired renal function (serum creatinine > 200)
2. Patients with severely impaired liver function
3. Serious intercurrent conditions or other nonmalignant illnesses that are uncontrolled or whose control may be affected by participation in this study
4. Any patient who has urinary or faecal incontinence
5. Previous history of cancer other than skin basal cell carcinoma

6. ECOG Performance Status >/= 3
7. Pregnant or breastfeeding women

Date of first enrolment
14/10/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Thomas Hospital
London
United Kingdom
SE1 7EH

Sponsor information

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

ROR
https://ror.org/00j161312

Funder(s)

Funder type
University/education

Funder Name
King's College London Health Partners (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration