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Biological magnetic resonance imaging parameters in cancer

Submission date 14/08/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/08/2017	**Overall study status** Completed	
Last Edited 23/04/2021	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-a-new-type-of-mri-scan-for-people-having-radiotherapy-for-throat-cancer-biopic

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
33659

Study information

Scientific Title

Biological magnetic resonance imaging parameters in oropharyngeal squamous cell carcinoma (BIOPIC): a non-randomised study

Acronym
BIOPIC

Study objectives
This study will investigate new MRI scanning techniques in patients undergoing radiotherapy treatment for squamous cell oropharyngeal (head and neck) cancer. We are looking at whether there are any changes in the cancer when the patient breathes in additional oxygen or carbogen (oxygen with carbon dioxide). This is important as tumours with low oxygen tend to be less responsive to treatment with chemotherapy or radiotherapy. We are also looking at a new method of imaging glucose (sugar) as this is taken up by cancer cells more than normal cells. We currently use FDG-PET/CT scans to image glucose but this involves radiation, unlike MRI. Patients will be asked to have an extra MRI scan before, during and after treatment to look at changes seen with the new MRI techniques we are investigating. We will also be taking blood samples and accessing tissue samples, such as routine biopsies taken as part of clinical care. We will look at the changes that occur with treatment, both under the microscope and through genetic testing. We will then compare this information to the findings from the MRI scans and other scans done routinely as part of patient care. We are interested to see if the new MRI techniques might be useful to monitor cancer patients having treatment or to predict whether they are likely to respond to therapy. In future this may allow us to choose the right treatment for a patient or to modify a treatment to improve response. This study is funded by the Oxford Cancer Imaging Centre and the Oxfordshire Health Services Research Committee. Recruitment will take place at the Churchill Hospital, Oxford.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gwasanaeth Moeseg Ymchwil Research Ethics Service, 08/02/2017, ref: 17/WA/0033

Primary study design
Interventional

Study design
Non-randomised; Both; Design type: Diagnosis, Process of Care, Imaging, Cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Head and Neck Cancer; UKCRC code/ Disease: Cancer/ Malignant neoplasms of lip, oral cavity and pharynx

Interventions
This is an observational study to assess novel MRI imaging techniques T1 and T2* with supplemental oxygen and carbogen breathing and CEST. Baseline scans will be compared to imaging during and post treatment in patients undergoing radiotherapy for oropharyngeal squamous cell carcinoma. For glucoCEST, comparison to DCE-MRI and contemporaneous clinical FDG-PET will also be undertaken. An exploratory study will investigate immunohistochemical

and genetic markers related to factors influencing response to radiotherapy and compare these to findings on imaging.

Patient will be recruited from a single centre (Oxford University Hospital Foundation Trust) and will receive standard treatment and follow-up as part of routine NHS care. 15 patients (group A) will undergo study MRI lasting no more than one hour at three time points (baseline, during and after radiotherapy). A subgroup of participants (group B) will have an additional MRI at baseline i.e. 4 study MRI scans in total. Every patient who agrees to participate in the study and is felt by the investigator to be suitable will be asked if they are willing to be part of group B until a total of 5 participants is reached. From seeking informed consent, patients will be followed until post-treatment imaging which takes place 10-12 weeks after completion of radiotherapy. The duration of patients participation will be approximately 4 months.

Intervention Type
Other

Primary outcome(s)
Changes in tumour T1 and T2* imaging with supplemental oxygen at baseline, week 2 radiotherapy and 10 weeks post radiotherapy

Key secondary outcome(s)
1. CEST signal with and without supplemental oxygen, measured at baseline, week 2 RT and 10 weeks post RT
2. T1, T2* and CEST signal with supplemental carbogen, measured at baseline, week 2 RT and 10 weeks post RT
3. Changes in GlucoCEST pre & post glucose load and markers such as choline, creatine, lactate, APT, measured at baseline, week 2 RT and 10 weeks post RT
4. FDG-PET parameters including SUVmax, uptake volume, measured at baseline and 10 weeks post RT
5. Standard DCE-MRI parameters such as ktrans, Ve, AUC compared with dynamic glucoCEST signal changes such as AUC, measured at baseline, week 2 RT and 10 weeks post RT
6. Consistency of MRI parameter measurements, evaluated using test-retest imaging at baseline in a subgroup of participants

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. HPV-positive oropharyngeal squamous cell carcinoma for treatment with radical radiotherapy +/- systemic therapy
4. The tumour is at least T2 or if nodal disease is used as the treatment assessment site, the node is at least 2 cm in minimum diameter on MRI
5. In the Investigator’s opinion, is able and willing to comply with all study requirements
6. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the study
7. Involvement in other clinical studies is acceptable

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Female participant who is pregnant, lactating or planning pregnancy during the course of the study
2. Significant renal or hepatic impairment
3. Type 1 diabetes mellitus or poorly controlled T2 diabetes mellitus or fasting capillary/venous blood glucose level > 8mmol/L.
4. Ongoing supplemental oxygen as part of clinical care
5. Known lung disease with carbon dioxide retention, chronic obstructive airways disease with known or at risk of hypercapnia
6. Most recent available arterial blood gas (ABG) from the current hospital admission demonstrates hypoxia or hypercapnia on room air
7. Any patient not felt to be suitable for supplemental oxygen or carbogen as considered by an appropriately trained clinician
8. Contraindication to MRI (e.g. cardiac pacemaker, ferromagnetic cerebral aneurysm clip, metallic foreign body in the eye)
9. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study

Date of first enrolment
24/04/2017

Date of final enrolment
06/09/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Oxford Imaging Trials Unit
United Kingdom
OX3 7LE

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version V03	21/10/2016	02/04/2019	No	No