

Biological magnetic resonance imaging parameters in cancer

Submission date 14/08/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/04/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

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

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

07/06/2016

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 20; UK Sample Size: 20

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

England

United Kingdom

Study participating centre

Oxford Imaging Trials Unit

United Kingdom

OX3 7LE

Sponsor information

Organisation

University of Oxford

Sponsor details

Clinical Trials and Research Governance

University of Oxford

Joint Research Office

Block 60

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England

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Sponsor type

University/education

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The intention is to publish this research in a specialist peer reviewed scientific journal on completion of the study. The results may also be presented at scientific meetings and/or used for a thesis. No study results may be published or presented without the prior approval of the TMG. Intend to publish before one year after overall trial end date.

Intention to publish date

31/05/2020

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?
Protocol file	version V03	21/10/2016	02/04/2019	No	No
HRA research summary			28/06/2023	No	No