ISRCTN58327080 https://doi.org/10.1186/ISRCTN58327080

Response assessment in head & neck cancer using multi-parametric Magnetic Resonance Imaging (MRI)

Submission date 12/01/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/02/2014	**Overall study status** Completed	
Last Edited 15/05/2023	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-using-different-scans-to-see-how-well-treatment-works-for-head-and-neck-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.3

Study information

Scientific Title
The accuracy of quantitative diffusion weighted MRI and 18F-FDG PET-CT in the prediction of locoregional residual disease following radiotherapy and chemoradiotherapy for head and neck cancer

Study objectives
It is hypothesized that residual areas of active disease may manifest as areas of lower ADC (restriction) or greater heterogeneity. The addition of diffusion weighted MRI and post processing techniques to quantify diffusion (ADC), may thus improve the accuracy of imaging in detecting residual cancer post treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Ethics Board: London Camberwell St Giles, 13/12/013, REC ref 13/LO/1876

Study design
Prospective cohort observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please contact adrian.green@gstt.nhs.uk to request a patient information sheet

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

Interventions
Patients will undergo MRI including diffusion-weighted MRI before treatment and at 6 and 12 weeks after completion of radiotherapy (RT) or chemoradiotherapy. Patients will undergo 18F-FDG PET-CT imaging at 12 weeks after completion of RT or chemoradiotherapy as per institutional protocol.
In addition to the standard 1.5 tesla MRI (using a surface phased array neck coil with T1w pre and post gadolinium/T1w fat sat post gadolinium and T2w axial, T1 fat saturated post gadolinium coronal and STIR coronal), a research DWI sequence will be added (matched images in the axial plane with multiple b values to enable assessment of the perfusive and diffusive fraction.

Further image analysis will be performed offline (Oncotreat, Siemens Healthcare, Erlangen, Germany). This will be both qualitative (presence/absence of hyperintensity relative to muscle), and quantitative (ADC0-1000 ADC0-150, ADC500-1000, ADChistogram,); for the tumour volume of interest. This will be assessed for the primary tumour and pathological (on the basis of standard staging criteria) nodal disease. ROIs will be delineated for the whole tumour volume and for ROIs that avoid areas of necrosis, where possible. Image processing will be performed on the acquired baseline and post treatment MRI and PET images using statistical and model based methods to assess for first and second order texture features. This will be performed using proprietary software developed in-house (FAST, KCL) to calculate exploratory measures including MGLI, skewness, kurtosis, SDH, run length matrix, uniformity, entropy and fractal dimension.
The 18F-FDG PET-CT scan will be performed as per standard clinical practice: Patients are fasted for at least 6 hours prior to administration of 350-400MBq 18F-FDG. PET-CT scans are acquired 90 minutes after injection from the upper thigh to the base of skull on one of two scanners (GE, Discovery VCT or DST). Images are reconstructed using OSEM with a reconstructed slice thickness of 3.27mm and pixel size of 5mm. The CT component of the scans is acquired for the same anatomical coverage without administration of oral or intravenous contrast agent for anatomical co-localisation.
Pathological evaluation, where available, will be obtained as per usual institutional practice. No additional biopsy will be required as part of the study. Consensus review of clinical and imaging findings (including interval CT and ultrasound imaging) will be performed at 24 months post treatment for all patients.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To compare quantitative DW-MRI with18F-FDG PET-CT in the prediction of locoregional residual disease following primary chemoradiotherapy or radiotherapy for stage 3 and 4 head and neck cancer

Secondary outcome measures
1.To assess whether different methods of calculating ADC (e.g. ADCperfusion, ADCdiffusion), and different methods of acquiring diffusion data can improve the prediction of residual disease
2. To assess if baseline ADC and changes in ADC from baseline to post treatment can improve prediction of residual disease
3. To determine if texture analysis, a post processing imaging technique, of acquired PET and MRI images to measure tumour heterogeneity can improve the prediction of residual disease
4. To compare DW-MRI parameters with standard structural MRI assessment for the prediction of residual disease
5. To correlate the quantitative MRI and PET-CT with locoregional progression-free survival (LPFS), disease-free survival (DFS) and overall survival (OS)
6. To determine if texture analysis (a post processing imaging technique of acquired standard and research MRI images to measure tumour heterogeneity) can improve the prediction of residual disease

Overall study start date
01/04/2014

Completion date
01/01/2020

Eligibility

Key inclusion criteria
1. Male or female, 18 years age or older
2. Stage 3 or 4 primary squamous cell carcinoma of the head and neck
3. One centimetre measurable area of primary or nodal tumour on the basis of standard clinico-radiological staging Eastern Cooperative Oncology Group (ECOG) performance status 0 to 2
4. The capacity to understand the patient information sheet and the ability to provide written informed consent see summary
5. Treatment with curative intent
6. Histologically confirmed squamous cell carcinoma

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
65

Key exclusion criteria
1. Standard contraindications to MRI and positron emission tomography computerised tomography (PET-CT)
2. Known allergy to Gadolinium contrast
3. Calculated glomerular filtration rate (GFR) (Cockroft or EDTA) < 30 mls/min
4. Prior chemotherapy or radiotherapy
5. Distant metastatic disease

Date of first enrolment
01/04/2014

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital
London
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SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. There are likely to be several publications.

Intention to publish date
01/01/2021

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		07/05/2021	10/05/2021	Yes	No
Plain English results			15/05/2023	No	Yes
HRA research summary			28/06/2023	No	No