

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

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

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

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

To compare quantitative DW-MRI with 18F-FDG PET-CT in the prediction of locoregional residual disease following primary chemoradiotherapy or radiotherapy for stage 3 and 4 head and neck cancer

Key secondary outcome(s)

1. To assess whether different methods of calculating ADC (e.g. ADC_{perfusion}, ADC_{diffusion}), 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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) (Cockcroft 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**

United Kingdom

England

Study participating centre

King's College Hospital

London

United Kingdom

SE5 9RS

Sponsor information

Organisation

King's College Hospital NHS Foundation Trust (UK)

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**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
HRA research summary			28/06/2023	No	No
Plain English results			15/05/2023	No	Yes