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

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

#### Contact name

Dr Stephen Connor

#### Contact details

Neuroradiology Department King's College Hospital Denmark Hill London United Kingdom SE5 9RS

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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 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

#### 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 clinicoradiological 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 United Kingdom SE5 9RS

# Sponsor information

#### Organisation

King's College Hospital NHS Foundation Trust (UK)

# Sponsor details

161 Denmark Hill London England United Kingdom SE5 9RS +44 (0)20 3299 1980 kch-tr.research@nhs.net

#### 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