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Detection of pseudoprogression using CT perfusion in patients with Glioblastoma Multiforme post-treatment

Submission date 20/04/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/07/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/06/2018	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-using-a-ct-scan-to-detect-false-growth-in-brain-tumours-after-treatment-ctpip

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Detection of pseudoprogression using CT perfusion in patients with Glioblastoma Multiforme post-treatment: an observational cohort study

Study objectives
This study will use CT perfusion scans to look for changes in the brain following treatment for a brain tumour. It is often difficult to detect changes in the brain that are caused as a result of the treatment effects, for example residual damage following radiosurgery may initially look like the tumour has progressed. Using CT perfusion techniques, additional physiological information relating to the tumour site can be acquired which will assist in the correct treatment management of the patient. It should be noted however that patients do not at present have a CT perfusion examination to assist in monitoring the progress of their tumour surveillance over their course of the patient's treatment, therefore this study would require additional ionising radiation, as the patients are only monitored using MRI perfusion techiques at this time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Haydock Research Ethics Committee, 01/06/2015, ref: 15/NW/0399

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Glioblastoma Multiforme

Interventions
A single CT perfusion scan will be carried out during the study. The study will be prospective and each patient will follow the procedure below:

Newly diagnosed patients with glioblastoma multiforme tumour will be given a neurosurgical referral, and then offered a course of treatment, depending on the classification of the tumour that will be either, or a combination of chemotherapy, radiosurgery or neurosurgery. After 3 months of treatment, the patient will undergo post-operative MRI. If the MRI scan shows no progression, the normal protocols will be followed. If the MRI scan shows tumour progression, they will have their case discussed at a multi-disciplinary team meeting (comprising neurosurgeons, neurologists, neuroradiologists and oncology nursing staff). If there is clinical progression (symptoms are reported to be present or worsening) present, an MRI perfusion scan will be performed and the clinical team will decide on further treatment management, which could include more surgery, radiotherapy or chemotherapy. If no clinical progression has been identified, the patient will undergo CT perfusion and MR perfusion on the same day, and be discharged. The CT and MRI perfusion scans will be reviewed and used for further management /monitoring. At 8 weeks post-treatment, if there is no clinical progression and no tumour progression on the scans, pseudoprogression of the tumour is likely. If after 8 weeks, there has been clinical symptom progression and this is seen on the scans, the patient will be followed up 8 weeks later. Incidence rate and frequency will be calculated using Two-tailed student t-test and ROC curve for analysis of sensitivity and specificity. Potential benefits include the timely and more accurate detection of pseudoprogression in this patient group, allowing changes relating to their treatment to be tailored accordingly. The sensitivity and specificity of CT perfusion in the differentiation between true tumour progression and pseudoprogression.

Intervention Type
Procedure/Surgery

Primary outcome measure
Diagnosis of true tumour progression measured by MRI scan 8 weeks after treatment

Secondary outcome measures
Better diagnosis and improved treatment options

Overall study start date
01/03/2015

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. Patients with glioblastoma multiforme tumours who will be discussed in the regional neuro-oncology multidisciplinary team meeting
2. Patients exhibiting any tumour progression on their first follow-up imaging immediately after radiotherapy, surgery or chemotherapy post-treatment without clinical progression

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
Patients who exhibit tumour progression both clinically (symptoms) and on imaging on the first follow-up imaging immediately following radiotherapy, chemotherapy or surgery following treatment

Date of first enrolment
01/05/2015

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Walton Centre NHS Foundation Trust
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05cvxat96

Funder(s)

Funder type
Government

Funder Name
The Walton Centre NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
We intend to dissemination the results hopefully by 2017 to all revalant parties but do not have any plans to publish as yet.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.2		09/05/2016	No	Yes
HRA research summary			28/06/2023	No	No