ISRCTN41243307 https://doi.org/10.1186/ISRCTN41243307

Feasibility of amide proton transfer imaging in children and adolescents with brain tumours

Submission date
21/01/2022

Recruitment status
No longer recruiting

Registration date
06/03/2022

Overall study status
Completed

Last Edited
29/04/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gliomas are brain tumours that start in glial cells. In children and adolescents diagnosed with gliomas, MRI scans are used to follow up patients which can be challenging, particularly when assessing a non-enhancing tumour. APT-CEST is a technique that can show an increased signal in non-enhancing parts of the tumour and the aim of this study is to correlate the APT-CEST signal with choline uptake as a marker of tumour activity.

Who can participate?
Children and adolescents aged 12-20 years being treated for glioma

What does the study involve?
Participation will involve the patient undergoing a PET-MRI scan. The participant will be injected with a radio-isotope named choline followed by an MRI scan. The MRI will be slightly longer than a normal diagnostic MRI at about 45 minutes. Following the PET-MRI scan, the patient will be free to go and will be followed up in clinic with their normal doctor.

What are the possible benefits and risks of participating?
The benefit for the patient will be an improved understanding of their tumour. The study will require extra time for scanning.

Where is the study run from?
University College London Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2015 to March 2020

Who is funding the study?
UCLH Biomedical Research Centre (UK)

Who is the main contact?
Dr Harpreet Hyare
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
162706

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 162706

Study information

Scientific Title
Feasibility of amide proton transfer chemical exchange saturation transfer in paediatric, teenage and young adult gliomas

Study objectives
Amide proton transfer (APT)-chemical exchange saturation transfer (CEST) demonstrated an elevated signal in brain tumours compared to normal-appearing brain tissue.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2016, London-Bromley Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8105; bromley.rec@hra.nhs.uk), REC ref: 16/LO/0276

Study design

Observational feasibility study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Glioma

Interventions
The participant is recruited from clinic by their normal doctor and is asked to undergo a PET-MRI study. The patient is given an information sheet and If the patient agrees, they are booked for a scan in the Nuclear Medicine Department. On the day of the scan, the patient is consented. The patient will have a canal fitted and be injected with radioactive choline. After 60 minutes, they will undergo a PET-MRI scan which is slightly longer than a normal MRI scan at approximately 45 minutes. The patient is then free to go and will be followed up by their normal doctor in clinic.

Intervention Type
Other

Primary outcome(s)
Glioma tumour cell proliferation measured using amide proton transfer chemical exchange saturation transfer (APT-CEST) and 18F-fluoromethylcholine (18F-choline) positron emission tomography (PET) standardised uptake value (SUV) at baseline

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/03/2020

Eligibility

Key inclusion criteria
Patients aged 12-20 years undergoing treatment for glioma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Pregnant
2. Other cancer

Date of first enrolment
01/04/2016

Date of final enrolment
01/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Research organisation

Funder Name
UCLH Biomedical Research Centre

Alternative Name(s)
NIHR University College London Hospitals Biomedical Research Centre, University College London Hospitals Biomedical Research Centre, UCLH/UCL Biomedical Research Centre, NIHR University College London Hospitals BRC, NIHR BRC, UCL, UCLH BRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes