

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

Submission date 21/01/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/03/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/04/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Dr Harpreet Hyare

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

162706

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a participation information sheet.

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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/09/2015

Completion date

01/03/2020

Eligibility

Key inclusion criteria

Patients aged 12-20 years undergoing treatment for glioma

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

10

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**

England

United Kingdom

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

Sponsor details

250 Euston Road
London
England
United Kingdom
WC1N 3PG
+44 (0)8451555000
semerton@nhs.net

Sponsor type

Hospital/treatment centre

Website

<https://www.uclh.nhs.uk/Pages/home.aspx>

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

Publication and dissemination plan

Peer-reviewed journal publication. Additional documents are not available.

Intention to publish date

01/03/2022

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