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Metabolic imaging of brain tumours using deuterium-labelled glucose

Submission date 18/04/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 05/07/2023	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 07/11/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Brain scans have made huge differences to the way brain tumours are diagnosed and treated. This study will build on this by using advanced MRI (Magnetic Resonance Imaging) to visualise the metabolism of brain tumours using a non-toxic specially modified form of glucose. Glucose is our most important source of energy. Glucose is made of carbon, hydrogen and oxygen atoms, and it can be modified to replace hydrogen atoms with non-toxic deuterium atoms (or “heavy” hydrogen atoms). This deuterium-labelled glucose has very similar biochemical characteristics to normal glucose but we can visualise its changing concentrations using MRI and also how it is broken down metabolically. This will help us understand how brain tumours metabolise glucose, which In the future, we hope that being able to visualise brain tumour metabolism will allow us to understand and visualise brain tumours in new ways. In the medium and long term, this could help reduce the need for surgical brain biopsies (samples), identify resistance to chemotherapy and reduce treatment-related side effects. However, to meet this goal we need to address fundamental questions about the feasibility of this approach. The main aim is - at this stage - to measure glucose metabolism in brain tumours after ingestion of modified deuterium-labelled glucose.

Who can participate?

Patients aged between 18 and 70 years referred to the East Midlands Neuro-Oncology /Haematology Service with a radiological diagnosis of a malignant brain tumour of a size that is measurable by the MRI scanner. Participants will be non-diabetic and are otherwise in good health with only minor symptoms or signs of their disease.

What does the study involve?

The intervention requires the participant to fast for 8-10 hours overnight. On the morning of the study, they will have their blood glucose measured with a simple finger-prick test. After this, they will drink 250 ml of flavoured non-toxic deuterium-labelled glucose. This contains the equivalent amount of added sugar as a large hot chocolate from a high street retailer. After 30 minutes, they will lie in the MRI scanner and measurements will be taken from the participant’s brain for no longer than 90 minutes. After the scan, participants will have another blood glucose finger-prick test and the participant will complete a questionnaire about their experience. Participants will be asked if they want to be recontacted and consider repeating the study after

3 months. The participant will then end the study and within 14 days of the end of the study, the participant's medical record will be reviewed to collect relevant information about their treatment and their brain tumour diagnosis. Participants will be asked if they want to be recontacted and consider repeating the study after 3 months. A small number of participants will be expected to repeat the study.

What are the possible benefits and risks of participating?
Beyond contributing to research intended to help other brain tumour patients in the long term, there are no expected direct benefits of participating in this study. Nevertheless, the opportunity to contribute to research and improve the lives of others can be a rewarding experience for many participants.
There are no recognised risks associated with the deuterium-labelling of the glucose. Glucose is a food product and the amount used in the study is equivalent to the amount of added sugars found in foods available on the high street. As such, the interventions in this study can be considered very low risk.
It is worth considering that the consumption of significant amounts of sugar can cause very high blood glucose levels (or paradoxically, low blood glucose levels). The risk of this will be reduced by excluding people with blood glucose disorders (e.g. diabetes mellitus), and measuring glucose levels after the scan has been completed.
The study will also involve taking part in research at an extraordinary time in the participant's life, where there will likely be significant anxiety surrounding diagnosis. Some people may find involvement in brain tumour research burdensome and upsetting. The psychological impact of participation will be mitigated by consulting care providers regarding patient suitability. Recruitment will also be conducted by a clinically trained member of the study team with experience in managing brain tumour patients.
The experience of an MRI can be claustrophobic and unpleasant and involves exposure to loud noises. Participants will have been already accustomed to MRI as part of their brain tumour treatment. Patients with claustrophobia will be excluded from the study and patients will be supplied with ear defenders. Patients will also have access to a microphone to communicate with the radiographer. Indeed, the team at Sir Peter Mansfield Imaging Centre (SPMIC) are exceptionally experienced with conducting imaging studies in a sensitive and caring manner.

Where is the study run from?
The Sir Peter Mansfield Imaging Centre (SPMIC), University Park, which is the main campus of University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
February 2023 to September 2028

Who is funding the study?
The University of Nottingham (UK)

Who is the main contact?
Mr Milo Hollingworth, milo.hollingworth@nottingham.ac.uk

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
313696

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 1.0, IRAS 313696

Study information

Scientific Title
Optimising deuterium magnetic resonance for in vivo assessment of cerebral glycolytic flux in brain tumours

Acronym
GLYCODMI-BT

Study objectives
Glycolytic flux in a malignant brain tumour can be distinguished from disease free brain using deuterated glucose and a 7T MRI scanner

Ethics approval required
Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design
Single-arm feasibility study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Malignant brain tumours

Interventions
Current interventions as of 07/11/2025:

Ingestion of 75 g deuterium-labelled glucose per kg body weight, dissolved in 250 ml of water followed by ~90 minute MRI scan.

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Previous interventions:

Ingestion of 0.75 g deuterium-labelled glucose per kg body weight, dissolved in 250 ml of water followed by ~90 minute MRI scan

Intervention Type
Supplement

Primary outcome(s)
Deuterium-labeled glucose and downstream metabolites and signal-to-noise ratio measured using magnetic resonance imaging/spectroscopy in the brain tumours compared to disease-free brain at a single timepoint

Key secondary outcome(s))
1. Deuterium-labelled glucose and downstream metabolites within different types of brain tumour (malignant glioma, brain metastasis and cerebral lymphoma) measured using magnetic resonance imaging/spectroscopy at a single timepoint
2. Deuterium-labelled glucose and downstream metabolites in brain tumours measured using magnetic resonance imaging/spectroscopy over time (3-6 months)
3. Tolerability of deuterium metabolic imaging measured using the MRI-Anxiety Questionnaire at a single timepoint

Completion date
01/09/2028

Eligibility

Key inclusion criteria

1. Radiological or tissue diagnosis of a malignant brain tumour
2. Aged 18-70 years
3. A tumour size detectable by the imaging sequence
4. Able to fully comprehend the informed consent process and give informed consent
5. Able to walk independently or with only minor support to the scanner (i.e. 10 metres without rest)
6. Able to carry on normal activity and to work with no special care needed. Normal activity some effort may be required and there may be some signs or symptoms of disease (Performance status >80)
7. Completed clinic or telephone screening
8. American Society of Anaesthesiologists (ASA) Physical Status Classification I or II; normal or healthy or with only mild systemic disease or mild diseases only without substantive functional limitations

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Likely to experience distress from participating in the study as assessed by the care provider
2. ASA Physical Classification Status III to IV; Severe systemic disease - moribund
3. A person who has received a diagnosis of Diabetes Mellitus defined as an 8 h fasting blood glucose ≥7.0 mmol/L (126 mg/dL), 2 h post 75 g oral glucose tolerance test (OGTT) ≥11.1 mmol/L (200 mg/dL), HbA1c ≥6.5% or in patients with symptoms of hyperglycaemic, a random plasma glucose of ≥11.1 mmol/L (200 mg/dL)
4. A person who has received a diagnosis of steroid-induced diabetes mellitus as an abnormal increase in blood glucose associated with the use of glucocorticoids in a patient with or without a prior history of diabetes mellitus.
5. A person who has received a diagnosis of pre-diabetes defined as a HbA1c of 5.7-6.4% or an second serum glucose measurement between 7.8- 11 mmol/L after an oral glucose tolerance test
6. Non-fluent English that would prohibit safe communication between the participant and radiographer via a microphone inside the scanner
7. Seizures within the last month despite anti-epileptic treatment
8. Inability to complete the MRI-Safety Questionnaire
9. Implantable medical cardiac, neurological devices (i.e. pacemaker, ICD, neurostimulator, aneurysm clip)
10. Having taken part in a research study in the last 3 months involving invasive procedures, ionising radiation or an inconvenience allowance. This excludes repeat particpants of the GLYCODMI Brain Tumour Study or the Tessa Jowell BRAIN MATRIX Study (NCT04274283), which is an observational platform study that biobanks tumour samples and blood for molecular analysis.
11. Having enrolment in GLYCODMI Brain Tumour Study and already completed two scans under study conditions

12. A symptom or condition that impedes lying flat for prolonged periods (90 minutes) (e.g. heart failure)
13. Cannot dress and undress independently

Date of first enrolment
01/09/2023

Date of final enrolment
01/09/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Nottingham
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Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham

Alternative Name(s)
The University of Nottingham

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes