ISRCTN14218060 https://doi.org/10.1186/ISRCTN14218060

Tessa Jowell BRAIN MATRIX - Platform Study

Submission date
13/01/2020

Recruitment status
Recruiting

Registration date
03/02/2020

Overall study status
Ongoing

Last Edited
16/05/2025

Condition category
Cancer

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

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-tissue-and-blood-samples-to-learn-more-about-glioma-tessa-jowell-brain-matrix

Plain English summary as of 02/01/2024:

Background and study aims
Gliomas, a type of brain tumour, are the most common primary tumour of the central nervous system (CNS) and in 2016 there were 5250 deaths from brain tumours in the UK. However, brain tumours are a challenging disease to treat. The tumour's location within the brain and its tendency to grow into nearby brain tissue often make it very difficult to remove the tumour completely with surgery. There is also difficulty in delivering drugs in adequate amounts to the tumour due to the natural defences of the brain.
Brain tumours arise due to changes in the DNA and other molecules in cells of the brain. Different types of gliomas can have different changes and these can be used to determine a precise 'molecular diagnosis'. The ultimate goal for the Tessa Jowell BRAIN MATRIX is to learn how to use these molecular changes to more precisely determine what exact type of tumour patients have, and to identify, decide and test whether specific 'targeted' treatments could improve the survival and/or quality of life of patients with brain tumours.
The Tessa Jowell BRAIN MATRIX is a programme of work, the principal purpose of which is to improve the knowledge of, and treatment for, glioma. The programme will include a Platform Study and subsequent interventional clinical trials. The Tessa Jowell BRAIN MATRIX Platform Study forms the backbone of this programme. In the Platform Study, the aim is to develop the infrastructure to provide rapid and accurate molecular diagnosis and the infrastructure to deliver clinical trials of new therapies in the future, thereby improving clinical outcomes in brain tumours.
The researchers aim to recruit 1,000 patients to the study. As gliomas occur at all ages and their specific subtype is hard to predict pre-operatively, the patient population eligible for the study is broad. A large network of clinical hubs across the UK, with expertise in managing patients with brain tumours, will be developed. Once established this infrastructure will facilitate the rapid introduction of clinical trials testing targeted therapies tailored to the genetic changes of an individual's tumour.

Who can participate?
Any patient aged over 16 years with newly diagnosed suspected WHO Grade 2-4 glioma, (as

evidenced radiologically) AND suitable for a diagnostic or therapeutic surgical procedure resulting in a tumour sample matched to a blood sample. Patients with progression with known WHO Grade 2-4 glioma (those with available frozen tumour) will be prioritised for detailed genomic analysis).

What does the study involve?
Eligible patients will either have had or be about to have surgery for their tumour. As part of this study, tumour removed during the operation will be analysed to look for specific molecular changes. As with normal standard care, the tumour will be analysed by a local pathologist. A small part will be sent for review by experts and advanced molecular analysis will be undertaken to get a detailed understanding of the DNA/molecular changes within the patient's tumour. These results will be fed back to the patient's treating doctor. It is intended that this will occur within 28 days; however, it may be longer while the study becomes fully operational. If samples are available from a patient's previous surgery on their tumour, these may also be analysed. Similarly, if available, other relevant samples such as cerebrospinal fluid, collected as part of their care, may also be analysed. In addition, as technologies and analyses improve the understanding of brain tumours, the researchers may find important results at a later date. These will be fed back to the patient's doctor. Patients will also be asked to give a blood sample, which will also be analysed to look at the molecular features, including their DNA. This is required to identify what 'new' changes have occurred in the patient's tumour. Following surgery, patients will continue with other treatment(s) as directed by their doctor. Treatment generally involves radiotherapy and chemotherapy. As is standard practice, patients will be closely monitored for signs of disease progression and the effects of the treatment given. As part of this study, information on patients' treatments and disease will be collected. Images from brain scans patients undergo, along with relevant clinical information, will also be sent to and stored by the University of Edinburgh, and where appropriate, undergo expert review by a panel of radiologists with expertise in brain tumours. If patients have further surgery, some of the tissue removed may also be analysed.

What are the possible benefits and risks of participating?
The researchers want to try and improve the outcome for patients with glioma and believe that providing this standardised platform may improve outcomes in, and options for, patients. However, it is possible that this may not show any benefit over the current UK standard practice.

Where is the study run from?
Cancer Research UK Clinical Trials Unit, University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
March 2019 to March 2027, with recruitment ending in March 2026

Who is funding the study?
The Brain Tumour Charity (UK)

Who is the main contact?
Mr Rhys Mant
brainmatrix@trials.bham.ac.uk

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Previous plain English summary as of 07/01/2021:

Background and study aims
Gliomas, a type of brain tumour, are the most common primary tumour of the central nervous

system (CNS) and in 2016 there were 5250 deaths from brain tumours in the UK. However, brain tumours are a challenging disease to treat. The tumour's location within the brain and its tendency to grow into nearby brain tissue often make it very difficult to remove the tumour completely with surgery. There is also difficulty in delivering drugs in adequate amounts to the tumour due to the natural defences of the brain.
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Who is the main contact?
Mr Rhys Mant
brainmatrix@trials.bham.ac.uk

Study website
https://www.birmingham.ac.uk/brainmatrix

Contact information

Type(s)
Scientific

Contact name
Mr Rhys Mant

Contact details
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Cancer Research UK Clinical Trials Unit
Institute of Cancer and Genomic Sciences
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Edgbaston
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B15 2TT
+44 (0)121 414 6788
brainmatrix@trials.bham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269228

ClinicalTrials.gov number
NCT04274283

Secondary identifying numbers
CPMS 44006, IRAS 269228

Study information

Scientific Title
A British feasibility study of molecular stratification and targeted therapy to optimize the clinical management of patients with glioma by enhancing clinical outcomes, Reducing avoidable toxicity, improving management of post-operative residual & recurrent disease and improving survivorship - Platform Study

Study objectives
Current study hypothesis as of 30/06/2022:
The main aim of the Tessa Jowell BRAIN MATRIX – Platform Study is to more precisely determine the exact type of tumour patients have by developing the essential infrastructure to provide rapid and accurate molecular diagnosis. A large network of clinical hubs across the

United Kingdom, with expertise in managing patients with brain tumours, will be developed. Once established this infrastructure will facilitate the rapid introduction of clinical trials testing targeted therapies tailored to the genetic changes of an individual's tumour.

Previous study hypothesis:
The main aim of the Tessa Jowell BRAIN MATRIX – Platform Study is to more precisely determine the exact type of tumour patients have by developing the essential infrastructure to provide rapid and accurate molecular diagnosis. A large network of clinical hubs across the UK, with expertise in managing patients with brain tumours, will be developed. Once established this infrastructure will facilitate the rapid introduction of clinical trials testing targeted therapies tailored to the genetic changes of an individual's tumour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2020, West Midlands – Edgbaston REC (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 1048089; NRESCommittee.WestMidlands-Edgbaston@nhs.net), REC ref: WM/19/0369

Study design
Observational; Design type: Genetic epidemiology

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Interventions
Current intervention as of 30/06/2022:
Research Pathway:
For patient's undergoing surgery, fresh tissue will be collected from the patient's initial surgery and frozen until shipment to the Oxford BRAIN MATRIX Laboratory. Matched blood sample for germline DNA will be taken following entry into the Platform Study. For patients with progression and have available tumour samples from previous tumour surgery, blood will be collected and submitted to the Oxford BRAIN MATRIX Laboratory along with their tumour samples.

Blood taken at Platform Entry and frozen tissue taken at first surgery will be shipped together to the Oxford BRAIN MATRIX Laboratory for molecular analysis, as follows:
1. Whole Genome Sequencing
2. EPIC array

The BRAIN MATRIX neuropathology and genomics team will generate an integrated report (histology, Whole Genome Sequencing, Heidelberg Classifier) for each case in consultation with the local neuropathology team. When this data is available, the BRAIN MATRIX neuropathology and genomics team will conduct a virtual MDT with the local referring site to ensure all relevant information will be incorporated in the final BRAIN MATRIX diagnostic report. The resulting integrated histological-molecular report will be available to local sites.

NHS Genomics Medicine Service Pathway:
Tessa Jowell BRAIN MATRIX centres in England can submit matched tissue and blood samples for Whole Genome Sequencing through the standard of care NHS Genomic Medicine Service (GMS) pathway via their Genomic Laboratory Hub (GLH). For those from Devolved Nations, samples must go to the Oxford BRAIN MATRIX Laboratory who can facilitate the processing of samples through an alternative NHS GMS GLH or via the research pathway.

For all patients:
Pseudoanonymised MRI for each patient will be collected and stored at a central imaging hub overseen by the Edinburgh Imaging Hub. Disease response assessment will be performed and additional analysis undertaken within permitted parameters.

Data will be collected on patients for up to 5 years from entry to the Platform Study where possible.

Previous intervention:
For patient's undergoing surgery, fresh tissue will be collected from the patient's initial surgery and frozen until shipment to the Oxford BRAIN MATRIX Laboratory. Matched blood sample for germline DNA will be taken following entry into the Platform study.

Patients who are not undergoing surgery and have available tumour samples from previous tumour surgery, blood will be collected and submitted to the Oxford BRAIN MATRIX Laboratory along with their tumour samples.

Blood taken at Platform entry and frozen tissue taken at first surgery will be shipped together to the Oxford BRAIN MATRIX Laboratory for molecular analysis, as follows:
1. Whole Genome Sequencing
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The BRAIN MATRIX neuropathology and genomics team will generate an integrated report (histology, Whole Genome Sequencing, Heidelberg Classifier) for each case in consultation with the local neuropathology team. When this data is available, the BRAIN MATRIX neuropathology and genomics team will conduct a virtual MDT with the local referring site to ensure all relevant information will be incorporated in the final BRAIN MATRIX diagnostic report. The resulting integrated histological-molecular report will be available to local sites.

Pseudoanonymised MRI for each patient will be collected and stored at a central imaging hub overseen by the Edinburgh Imaging Hub. Disease response assessment will be performed and additional analysis undertaken within permitted parameters.

Data will be collected on patients for up to 5 years from entry to the Platform Study where possible.

Intervention Type
Genetic

Primary outcome measure
Current primary outcome measure as of 16/05/2025:

1. Time (from biopsy) to integrated histological–molecular diagnosis (TTMD) using standard of care NHS practice, defined as the difference (days) between date of biopsy and date of final local pathology report, measured within 28 days.
2. Time (from biopsy) to Whole Genome Sequencing report to the treating clinician using NHS Genomic Medicine Service, defined as the different (days) between date of biopsy and date that a patient's Genomic Tumour Advisory Board (GTAB) report is produced, measured within 28 days.

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Previous primary outcome measure as of 30/06/2022:
Time (from biopsy) to integrated histological–molecular diagnosis (TTMD), defined as the difference (days) between dates of biopsy and date of whole genome diagnosis and epigenomic classification, measured within 28 days.

Previous primary outcome measure:
Time (from biopsy) to integrated histological – molecular diagnosis (TTMD), defined as the difference (days) between dates of biopsy and whole genome diagnosis and epigenomic classification, measured within 28 days.

Secondary outcome measures
Current secondary outcome measures as of 30/06/2022:
Secondary outcome measures to be achieved within a timescale of up to 5 years:
1. Time to completion of each node of tissue and imaging pathway, measured from the date of receipt at the current node to date of delivery at the next.
2. Tumour and biological sample(s) quality control (QC) status: tumour and biological sample collection will be measured against protocol guidelines. These data will be collected in the surgical and pathological forms.
3. Imaging QC status: imaging will be measured against established clinical guideline. The imaging form will measure compliance against these guidelines.
4. Inter-rater agreement of Response Assessment in Neuro-Oncology (RANO): scans will be assessed and scored according to RANO criteria by the hub of Neuro-radiologists.

Patient-centred outcome measures to be achieved within a timescale of up to 5 years:
1. Extent of surgical resection, evaluated from the post-operative MRI scan and categorised as follows: Closed biopsy, open biopsy, debulking <50%, subtotal resection 50-90%, near total resection 90-<100%, gross total resection 100%.
2. Overall survival time, defined as the time from date of diagnosis to the date of death. Patients who are alive at the time of analysis will be censored at the date last seen in clinic.
3. Intracranial progression-free survival time, defined as the time from date of registration to the earliest of date of intracranial progressive disease or death from disease. The date of an event is defined as the earliest confirmation of progression by radiological assessment, clinical symptoms or MDT. Patients without progression will be censored at the date last seen in clinic.

4. Quality of Life scores: longitudinal measures of QoL will be generated from the QoL questionnaire according to the questionnaire-specific algorithm for scoring.
5. Type of interventions received, monitored throughout the follow-up period and recorded on the CRF.
6. Type of complications from treatments (standard of care) received (e.g. surgical wound infection), monitored throughout the follow-up period and recorded on the CRF.
7. Concordance of diagnoses: any difference between the tiers of diagnoses will be highlighted and categorised as: discordant; agreed; refined

Research framework outcome measures to be achieved within a timescale of up to 5 years:
1. Samples and images centrally stored
2. Targetable mutation(s) identified by WGS and EC
3. Post-mortem sampling consent status and sample collection confirmation, based on receipt of post-mortem consent form, and on post-mortem samples with confirmed central storage.
4. Number of applications to, and outputs resulting from data repository

Previous secondary outcome measures:
Secondary outcome measures to be achieved within a timescale of up to 5 years:
1. Time to completion of each node of tissue and imaging pathway, measured from the date of receipt at the current node to delivery at the next
2, Tumour and biological sample(s) QC status: tumour and biological sample collection will be measured against protocol guidelines. These data will be collected in the surgical and pathological forms.
3. Imaging QC status: imaging will be measured against established clinical guideline. The imaging form will measure compliance against these guidelines.
4. Inter-rater agreement of RANO assessments: scans will be assessed and scored according to RANO criteria by the hub of Neuro-radiologists (see imaging protocol).

Patient-centred outcome measures to be achieved within a timescale of up to 5 years::
1. Extent of surgical resection calculated as follows:
Volume removed = initial volume before surgery – residual volume after surgery (based on imaging obtained within 72 hours of surgery)
2. Overall survival time, defined as the time from date of diagnosis to the date of death. Surviving patients will be censored at the date last seen in clinic
3. Intracranial progression-free survival time, defined as the time from date of registration to the earliest of date of Intracranial progressive disease or death from disease. The date of an event is defined as the earliest confirmation of progression by radiological assessment, clinical symptoms or MDT. Patients without progression will be censored at the date last seen in clinic.
4. Quality of life: longitudinal QoL data will be scored according to the questionnaire-specific algorithm.
5. Type of interventions received (e.g. surgical wound infection) monitored throughout the follow-up period and recorded on the CRF
6. Type of complications from treatments (standard of care) received (e.g. surgical wound infection) monitored throughout the follow-up period and recorded on the CRF
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2. Targetable mutation(s) identified by WGS and EC

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4. Number of applications to, and outputs resulting from data repository

Overall study start date
01/03/2019

Completion date
01/03/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 03/01/2024:
1. Any patient ≥16 years
2. Newly diagnosed suspected WHO Grade 2-4 glioma, (as evidenced radiologically) AND suitable for a diagnostic or therapeutic surgical procedure resulting in a tumour sample matched to a blood sample
3. Patients with progression with known WHO Grade 2-4 glioma (those with available frozen tumour will be prioritised for detailed genomic analysis)
4. Valid written informed consent for the study

Previous inclusion criteria from 07/01/2021 to 03/01/2024:
1. Newly diagnosed suspected WHO Grade 2-4 glioma, (as evidenced radiologically) AND suitable for a diagnostic or therapeutic surgical procedure resulting in a tumour sample matched to a blood sample
2. Patients with progression with known WHO Grade 2-4 glioma (those with available frozen tumour will be prioritised for detailed genomic analysis)
3. Valid written informed consent for the study

Original inclusion criteria:
1. Newly diagnosed suspected glioma, (as evidenced radiologically) AND suitable for a diagnostic or therapeutic surgical procedure resulting in a tumour sample matched to a blood sample
2. Patients with progression with known Grade 2-4 glioma (those with available frozen tumour will be prioritised for detailed genomic analysis)
3. Valid written informed consent for the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex

Both

Target number of participants
Planned Sample Size: 1,000; UK Sample Size: 1,000

Key exclusion criteria
1. Primary spinal cord tumours
2. Active treatment of other malignancy
3. Contraindication to MRI
4. Patients without standard of care imaging available (added 07/01/2021)

Date of first enrolment
24/11/2020

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Queen Elizabeth Hospital Birmingham (lead centre)
University Hospital Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2WB

Study participating centre
Western General Hospital
NHS Lothian
Crewe Road South
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Royal Infirmary of Edinburgh
NHS Lothian
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Queen Elizabeth University Hospital
NHS Greater Glasgow and Clyde Health Board
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett St
Leeds
United Kingdom
LS9 7TF

Study participating centre
The Walton Centre
Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7LJ

Study participating centre
King's College Hospital
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Salford Royal Hospital
Northern Care Alliance NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
The Christie
The Christie NHS Foundation Trust
Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre
Queen's Medical Centre
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre

Churchill Hospital
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Velindre Cancer Centre
Velindre Road
Cardiff
United Kingdom
CF14 2TL

Sponsor information

Organisation
University of Birmingham

Sponsor details
Research Support Group
Aston Webb Building (B Block)
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 415 8011
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Brain Tumour Charity

Alternative Name(s)
The Brain Tumour Charity

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication

Intention to publish date
01/03/2027

Individual participant data (IPD) sharing plan

Current individual participant data (IPD) sharing statement as of 30/06/2022:
Scientifically sound proposals from appropriately qualified researchers will be considered for data sharing. Requests should be made by returning a Data Sharing Request Form to newbusiness@trials.bham.ac.uk; this captures the research requirements, statistical analysis plan, and intended publication schedule. Requests will be reviewed by the Cancer Research UK Clinical Trials Unit (CRCTU) Directors in discussion with the Chief Investigator (CI), Study Management Group (SMG) and independent Scientific Advisory Board (SAB). They will consider the scientific validity of the request, qualifications of the researchers, CI, SMG & SAB views, consent arrangements, practicality of anonymizing the requested data & contractual obligations. If supportive of the request, and where not already obtained, Sponsor consent for data transfer will be sought before notifying applicants of the outcome. It is anticipated that applicants will be notified within 3 months of receipt of the original request.

Previous individual participant data (IPD) sharing statement:
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/09/2022	27/09/2022	Yes	No