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A clinical trial adding Sativex (a cannabis-based medicine) to standard treatment, temozolomide, to find out if it is beneficial for patients whose glioblastoma brain tumour has returned after treatment

Submission date 20/09/2022	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 25/10/2022	**Overall study status** Ongoing	
Last Edited 28/01/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Glioblastoma multiforme (GBM) is a type of brain tumour. When it is first diagnosed, patients are usually treated with surgery and then a combination of radiotherapy and chemotherapy with temozolomide. Unfortunately, although this often slows or stops the disease from growing for a period of time, in most cases, usually a few months after the end of the original treatment, the tumour starts to grow again. This can be detected by a magnetic resonance imaging (MRI) scan (a type of imaging that visualises the internal structures). When this happens patients may experience new symptoms or a repeat of previous symptoms.

There are few treatments available that work well at this stage to slow the growth of the tumour. Therefore, we need to develop new and better treatments to make patients live longer and feel better. The ARISTOCRAT trial is investigating whether adding a second drug (Sativex, a cannabinoid or cannabis-based medicine) to the drug already used, temozolomide, works better than temozolomide alone. Temozolomide is the chemotherapy drug that patients will have had before, both with radiotherapy and then afterwards by itself.

In a small trial already completed investigating the combination of temozolomide and Sativex, there were some interesting results suggesting that taking both drugs together was safe to give and may have an effect on the growth of brain tumours. To see if this treatment does work we need to do a much larger trial and compare the new treatment (temozolomide plus Sativex) to temozolomide (temozolomide plus placebo).

Who can participate?
Patients aged 16 years old and over with recurrent GBM

What does the study involve?
The study will find out whether the addition of Sativex to standard temozolomide treatment improves how long patients live, delays the growth of their tumours and/or improves their quality of life.

What are the possible benefits and risks of participating?
We cannot promise that you will benefit directly from participating in this trial. It is possible that the treatment you receive will be more effective or have different side effects. However, we will not know this until the results of the trial are available. All the information that we get from this trial will help improve the treatment of patients with recurrent glioblastoma in the future.

There is a risk that there is no clinical benefit to a patient receiving trial treatment. However, there is also the possibility that the results may be positive and that the treatment may cause tumour shrinkage and/or prolong survival. Patients will be made fully aware of this both verbally, and in written communication within the Patient Information Sheet (PIS).
Patients in this trial will be at risk of side effects or toxicity of temozolomide, Sativex and potential unknown risks due to the combination of the two drugs. These drugs have been used in combination in a Phase I study and no significant concerns were raised. The toxicity profile of both drugs in monotherapy is well-known and documented. Any adverse events experienced by the patients will be reviewed at each clinic visit. Patients are also advised in the PIS to notify their trial doctor or research nurse immediately if they experience any of the side effects listed in the PIS. Adverse Events that are related to the Investigational Medicinal Products and Serious Adverse Events will be recorded and reported to the ARISTOCRAT Trial Office.
During the trial, patients will have routine blood samples taken during the trial to assess ongoing safety. The risks of having blood taken from a vein include pain, bruising or infection at the site where the blood was taken, and fainting. Blood samples will be grouped as much as possible to minimise the number of times blood is taken to reduce risk to patients.
Effects on operating machinery: There is a risk that temozolomide and Sativex may affect patients' ability to use machines safely. This is because the drugs may cause them to feel tired or dizzy, which may impair their judgement and performance of skilled tasks. Patients should not operate machinery or tools if they have side effects such as tiredness, sleepiness or dizziness. Furthermore, patients with recurrent GBM are not permitted to drive. Patients will be made fully aware of this in written communication within the PIS.
There is a risk that if a patient (or their partner) becomes pregnant while receiving trial treatment or immediately after, the unborn baby could be affected. For this reason, sites will ensure that all females of childbearing potential undergo a pregnancy test prior to receiving trial medications. All patients with childbearing potential will be educated regarding the need for adequate contraception whilst they are receiving trial drugs and for at least 6 months afterwards. Should a patient become pregnant whilst receiving trial treatment, treatment will be stopped and the pregnancy outcome will be monitored. If a patient's partner becomes pregnant during this period, we would also like to collect details of the outcome of the pregnancy with their permission.
All staff involved in the trial are fully aware of the importance of confidentiality and the Caldicott principles. Patient confidentiality will be maintained at all times during participation in the trial and once the patient has completed the trial. Under no circumstances will any patient identifiers be published. Patients are made aware of the patient information sheet and asked to consent to the personal identifiers that may be used on trial documentation and trial samples.
The trial will be conducted in accordance with the UK Policy Framework for Health and Social Care Research, the applicable UK Statutory Instruments, (which include the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679 and the Data Protection Act 2018) and GCP.

Sativex/placebo will be shipped to sites unblinded. Blinding will be performed by local pharmacies, who could reveal treatment allocation to patients, the clinical team or CRCTU staff. Unblinding must be approved by a consultant-level clinician. Results of urine testing for other cannabinoid use are for research purposes only, but could unblind the trial data so will not be provided to the patient, clinical team or trials office, except to one delegated staff member not working on the trial. Cannabinoids are not routinely tested except for legal reasons; GPs will be advised not to share the presence of cannabinoids if it shows in a patient's blood or urine. Patients will complete additional Health-Related Quality of Life (HRQoL) questionnaires. There is a risk that the patient may be unable to complete the HRQoL questionnaires or become upset when completing them. Prior to completing each HRQoL questionnaire, a member of the Site Research Team should discuss the questionnaires with the patient and answer any questions they may have. If a participant requires assistance from a caregiver or member of the Site Research Team, this should be recorded on the HRQoL Booklet.
Urine testing for cannabinoid use is above the standard of care. Urine tests will be performed by the patient during their clinic visit, with support from site staff if necessary. A urine test is considered a safe and non-invasive form of testing and there is no risk associated with these tests.

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?
August 2022 to April 2027

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

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

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-sativex-for-people-with-glioblastoma-aristocrat

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Fiona Collinson

ORCID ID
https://orcid.org/0000-0003-4423-7256

Contact details
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
Leeds
United Kingdom

LS9 7TF
+44(0)113 32068811
F.J.Collinson@leeds.ac.uk

Type(s)
Public

Contact name
Mr Rhys Mant

Contact details
ARISTOCRAT Trial Office
Cancer Research UK Clinical Trials Unit
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 6788
aristocrat@trials.bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2021-005214-34

Integrated Research Application System (IRAS)
1004427

ClinicalTrials.gov (NCT)
NCT05629702

Protocol serial number
RG_21-001

Central Portfolio Management System (CPMS)
52902

Study information

Scientific Title
A randomised controlled phase II trial of temozolomide with or without cannabinoids in patients with recurrent glioblastoma

Acronym
ARISTOCRAT

Study objectives
To establish whether the addition of cannabinoids (Sativex) to standard temozolomide (TMZ) treatment improves overall survival time (OS) in MGMT methylated recurrent glioblastoma multiforme compared to the addition of placebo to TMZ.

To establish the impact of adding cannabinoids to TMZ in terms of progression-free survival time (PFS), health-related quality of life (HRQoL) and adverse events in this setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/10/2022, London - Westminster REC (Health Research Authority, Equinox House, City Link, Nottingham Centre, NG2 4LA, UK; +44 (0)207 104 8066; westminster.rec@hra.nhs.uk), ref: 22/LO/0630

Study design
Randomized placebo-controlled double-blind parallel-group study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
All patients in Arm 1 and Arm 2 will receive standard temozolomide (TMZ). This is 150mg/m2 for cycle 1, increasing to 200mg/m2 for subsequent cycles, once daily for days 1-5 orally at the start of each 28-day cycle, up to a maximum of 6 cycles. In addition to standard TMZ, patients will receive Sativex or Sativex-matched placebo, up to 12 sprays per day up to a maximum of 6 cycles, self-titrated over days 1-14 in cycle 1.

Patients will be randomised to trial medication in a double-blinded manner using a computer minimisation technique developed by CRCTU.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Sativex (cannabinoids), temozolomide

Primary outcome(s)
Overall survival time (OS), defined as the time in whole days from the date of randomisation to the date of death from any cause, measured using patient survival until the date of death. Patients who are alive at the time of analysis will be censored at the date last seen alive.

Key secondary outcome(s))
1. Overall survival measured using patient survival at 12 months (and 6 and 24 months)
2. Progression-free survival time, defined as the time in whole days from the date of

randomisation to the date of the first documented evidence of disease progression or death (from any cause), measured using Response Assessment for Neuro-Oncology (RANO) criteria at screening, weeks 10, 22, 30 then 3 monthly (as per standard of care) for up to a minimum of 52 weeks from the start of trial treatment
3. Health-related quality of life measured using the EORTC QLQ-C30, EORTC BN20, single items from the EORTC item library, and the EQ-5D-5L at screening and then every 8 weeks until the end of treatment
4. Adverse events measured using CTCAE v5.0 at 4-weekly intervals post-start of treatment up to progression or withdrawal

Completion date
30/04/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/06/2025:
1. Histological diagnosis of MGMT promoter methylated, IDH wild type (WT) glioblastoma multiforme (GBM) with consistent local molecular pathology (repeat biopsy at recurrence is NOT required)
2. First recurrence of GBM planned for systemic treatment as determined by local Multidisciplinary Team (MDT), including agreement of a Consultant Neuro-Radiologist that imaging changes are most in keeping with recurrence and not pseudo-progression and patient is planned for systemic treatment. Patients with a prior recurrence treated by surgical resection alone are eligible at time of first recurrence planned for systemic treatment.
3. Patients must have received initial first-line treatment with standard dose conventionally fractionated radiotherapy (i.e., 40 Gy in 15 fractions or 54-60 Gy in 28-33 fractions; other regimes may be considered in consultation with the ARISTOCRAT Trial Office) with concomitant and adjuvant temozolomide (TMZ)
3.1 Minimum of 3 cycles of adjuvant TMZ must have been received
3.2. Minimum of Stable Disease (SD) (or Partial Response (PR)/Complete Response (CR)) at the end of first-line treatment
4. ≥3 months since day 28 of the last cycle of TMZ
5. Karnofsky Performance Status ≥60
6. Adequate hematologic, renal, and hepatic function within 14 days prior to randomisation:
6.1. Absolute neutrophil count (ANC) ≥1.5 x 109/L
6.2. Platelet count ≥100 x 109/L
6.3. Serum creatinine clearance (measured or calculated (using local standard practice)) >30 ml /min
6.4. Total serum bilirubin ≤1.5 x upper limit of normal (ULN)
6.5. Liver transaminases <2.5 x ULN
7. If surgery has been performed for first recurrence then the wound must be adequately healed and there must be residual enhancing disease on MRI within 21 days of surgery or new enhancement at later follow-up deemed suitable for systemic treatment
8. Recovered from previous treatment side-effects ≤ Grade 2
9. If on systemic steroids, must be on stable (≥7 days) or decreasing dose of steroids
10. Willing and able to provide trial-specific informed consent
11. Willing and able to comply with trial requirements
12. Aged 16 years old and over
13. Able to start treatment within 28 days of randomisation

Previous inclusion criteria as of 31/08/2023:
1. Histological diagnosis of MGMT promoter methylated, IDH wild type (WT) glioblastoma multiforme (GBM) with consistent local molecular pathology (repeat biopsy at recurrence is NOT required)
2. First recurrence of GBM planned for systemic treatment as determined by local Multidisciplinary Team (MDT), including agreement of a Consultant Neuro-Radiologist that imaging changes are most in keeping with recurrence and not pseudo-progression and patient is planned for systemic treatment. Patients with a prior recurrence treated by surgical resection alone are eligible at time of first recurrence planned for systemic treatment.
3. Patients must have received initial first-line treatment with standard dose conventionally fractionated radiotherapy (i.e., 40 Gy in 15 fractions or 54-60 Gy in 28-33 fractions; other regimes may be considered in consultation with the ARISTOCRAT Trial Office) with concomitant and adjuvant temozolomide (TMZ)
3.1 Minimum of 3 cycles of adjuvant TMZ must have been received
3.2. Minimum of SD (or PR/CR) at the end of first-line treatment
4. ≥3 months since day 28 of the last cycle of TMZ
5. Karnofsky Performance Status ≥60
6. Adequate hematologic, renal, and hepatic function within 14 days prior to randomisation:
6.1. Absolute neutrophil count (ANC) ≥1.5 x 109/L
6.2. Platelet count ≥100 x 109/L
6.3. Serum creatinine clearance (measured or calculated (using local standard practice)) >30 ml /min
6.4. Total serum bilirubin ≤1.5 x upper limit of normal (ULN)
6.5. Liver transaminases <2.5 x ULN
7. If surgery has been performed for first recurrence then the wound must be adequately healed and there must be residual enhancing disease on MRI within 21 days of surgery or new enhancement at later follow-up deemed suitable for systemic treatment
8. Recovered from previous treatment side-effects ≤ Grade 2
9. If on systemic steroids, must be on stable (≥7 days) or decreasing dose of steroids
10. Willing and able to provide trial-specific informed consent
11. Willing and able to comply with trial requirements
12. Aged 16 years old and over
13. Able to start treatment within 28 days of randomisation

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1. Histological diagnosis of MGMT promoter methylated, IDH wild type (WT) glioblastoma multiforme (GBM) with consistent local molecular pathology (repeat biopsy at recurrence is NOT required)
2. First recurrence of GBM planned for systemic treatment as determined by local Multidisciplinary Team (MDT), including agreement of a Consultant Neuro-Radiologist that imaging changes are most in keeping with recurrence and not pseudo-progression and patient is planned for systemic treatment. Patients with a prior recurrence treated by surgical resection alone are eligible at time of first recurrence planned for systemic treatment.
3. Patients must have received initial first-line treatment with standard dose conventionally fractionated radiotherapy (i.e. 54-60 Gy in 28-33 fractions) with concomitant and adjuvant temozolomide (TMZ) (STUPP regime)
3.1 Minimum of 3 cycles of adjuvant TMZ must have been received
3.2. Minimum of SD (or PR/CR) at the end of first-line treatment
4. ≥4 months since day 28 of the last cycle of TMZ
5. Karnofsky Performance Status ≥60
6. Adequate hematologic, renal, and hepatic function within 14 days prior to randomisation:
6.1. Absolute neutrophil count (ANC) ≥1.5 x 109/L

6.2. Platelet count ≥100 x 109/L
6.3. Serum creatinine clearance (measured or eGFR) >30ml/min
6.4. Total serum bilirubin ≤1.5 x upper limit of normal (ULN)
6.5. Liver transaminases <2.5 x ULN
7. If surgery has been performed for first recurrence then the wound must be adequately healed and there must be residual enhancing disease on MRI within 21 days of surgery or new enhancement at later follow up deemed suitable for systemic treatment
8. Recovered from previous treatment side-effects ≤ Grade 2
9. If on systemic steroids, must be on stable (≥7 days) or decreasing dose of steroids
10. Willing and able to provide trial-specific informed consent
11. Willing and able to comply with trial requirements
12. Aged 16 years old and over
13. Able to start treatment within 28 days of randomisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 06/06/2025:
1. Pathology inconsistent with IDH WT glioblastoma multiforme (GBM) (e.g. patients with molecular features of PXA or BRAF mutation will be excluded)
2. Prior invasive malignancy (except non-melanoma skin cancer), unless disease free for a minimum of one year
3. Prior treatment with stereotactic radiotherapy, brachytherapy or Convection Enhanced Delivery (CED) of any agent
4. Prior treatment, apart from debulking surgery, for first recurrence of GBM
5. Any active co-morbidity making patient unsuitable for trial treatment in the view of the Investigator
6. Personal history of schizophrenia, other psychotic illness, severe personality disorder or other significant psychiatric diagnosis other than depression associated with their underlying glioma condition
7. Prior allergic reaction or significant toxicity (≥Grade 3 CTCAE) related to temozolomide treatment

8. Current or recent cannabis or cannabinoid-based medications within 28 days of randomisation and/or unwilling to abstain for the duration of the trial
9. Women who are pregnant, breastfeeding or a woman of childbearing potential who is unwilling to use effective contraceptive methods during trial treatment and for 6 months after completion of trial treatment
9.1. Women of childbearing age must have a negative pregnancy test within 7 days prior to randomisation
10. Men who are sexually active and unwilling/unable to use medically acceptable forms of contraception during trial treatment or for 6 months after completion of trial treatment
11. Contraindication to MRI or gadolinium
12. Hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption
13. Known hypersensitivity to cannabinoids or excipients of the IMP
14. Known history of current or prior alcohol or drug dependence
15. Known Hepatitis B (HBV), Cytomegalovirus (CMV) or opportunistic infection
16. Has received a live vaccine within 28 days prior to randomisation
17. Unable to administer oromucosal medication due to mucosal lesions or other issues
18. Participation in another therapeutic clinical trial whilst taking part in this trial
19. Any psychological, familial, sociological or geographical condition hampering protocol compliance

Previous exclusion criteria as of 08/11/2022:
1. Pathology inconsistent with IDH WT glioblastoma multiforme (GBM) (e.g. patients with molecular features of PXA or BRAF mutation (on original pathology) will be excluded)
2. Prior invasive malignancy (except non-melanoma skin cancer), unless disease free for a minimum of one year
3. Prior treatment with stereotactic radiotherapy, brachytherapy or Convection Enhanced Delivery (CED) of any agent
4. Prior treatment, apart from debulking surgery, for first recurrence of GBM
5. Any active co-morbidity making patient unsuitable for trial treatment in the view of the Investigator
6. Personal history of schizophrenia, other psychotic illness, severe personality disorder or other significant psychiatric diagnosis other than depression associated with their underlying glioma condition
7. Prior allergic reaction or significant toxicity (≥Grade 3 CTCAE) related to temozolomide treatment
8. Current or recent cannabis or cannabinoid-based medications within 30 days of randomisation and/or unwilling to abstain for the duration of the trial
9. Women who are pregnant, breastfeeding or a woman of childbearing potential who is unwilling to use effective contraceptive methods during trial treatment and for 6 months after completion of trial treatment
9.1. Women of childbearing age must have a negative pregnancy test within 7 days prior to randomisation
10. Men who are sexually active and unwilling/unable to use medically acceptable forms of contraception during trial treatment or for 6 months after completion of trial treatment
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14. Known history of current or prior alcohol or drug dependence
15. Known Hepatitis B (HBV), Cytomegalovirus (CMV) or opportunistic infection
16. Has received a live vaccine within 28 days prior to randomisation
17. Unable to administer oromucosal medication due to mucosal lesions or other issues
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13. Known hypersensitivity to cannabinoids or excipients of the IMP
14. Known history of current or prior alcohol or drug dependence
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16. Participation in another therapeutic clinical trial whilst taking part in this trial
17. Any psychological, familial, sociological or geographical condition hampering protocol compliance

Date of first enrolment
03/02/2023

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow
Scotland
G12 0YN

Study participating centre
Bristol Haematology & Oncology Centre
Horfield Road
Bristol
England
BS2 8ED

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

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
England
NG5 1PB

Study participating centre
Clatterbridge Cancer Centre
Clatterbridge Road
Wirral
England
CH63 4JY

Study participating centre
Guy's Hospital
Great Maze Pond
London
England
SE1 9RT

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2TH

Study participating centre
St James University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
The Christie
550 Wilmslow Road
Withington
Manchester
England
M20 4BX

Study participating centre
Velindre Cancer Centre
Velindre Road
Cardiff

Wales
CF14 2TL

Study participating centre
Churchill Hospital
Churchill Hospital
Old Road
Headington
Oxford
England
OX3 7LE

Study participating centre
Mount Vernon Cancer Centre
Rickmansworth Road
Northwood
England
HA6 2RN

Study participating centre
Castle Hill Hospital
Queens Centre
Cottingham
Hull
England
HU16 5JQ

Study participating centre
Derriford Hospital
Derriford Road
Plymouth
England
PL6 8DH

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
Scotland
AB25 2ZN

Study participating centre
St. Bartholomews Hospital
West Smithfield
London
England
EC1A 7BE

Study participating centre
Maidstone
Maidstone Hospital
Hermitage Lane
Maidstone
England
ME16 9QQ

Sponsor information

Organisation
University of Birmingham

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
Jazz Pharmaceuticals

Alternative Name(s)
Jazz Pharmaceuticals plc, Greenwich Biosciences, Jazz Pharmaceuticals, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
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), Trial Management Group (TMG) and independent Trial Steering Committee (SAB). They will consider the scientific validity of the request, qualifications of the researchers, CI, TMG & TSC 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.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/01/2024	16/01/2024	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes