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# A prospective randomised trial comparing temozolomide with standard nitrosourea-based chemotherapy (PCV [procarbazine, CCNU, vincristine]/BCNU [bis-chloronitrosourea]) in the treatment of recurrent WHO astrocytic tumours grades III and IV (anaplastic astrocytoma and glioblastoma multiforme)

**Submission date**
21/09/2000

**Recruitment status**
No longer recruiting

**Registration date**
21/09/2000

**Overall study status**
Completed

**Last Edited**
05/10/2018

**Condition category**
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-temozolomide-and-pcv-for-people-with-glioma-that-has-come-back-after-treatment

**Study website**
http://www.ctu.mrc.ac.uk/studies/BR12.asp

## Contact information

**Type(s)**
Scientific

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# Additional identifiers

### EudraCT/CTIS number
2005-004622-24

### IRAS number

### ClinicalTrials.gov number
NCT00052455

### Secondary identifying numbers
E164/47

# Study information

### Scientific Title
A prospective randomised trial comparing temozolomide with standard nitrosourea-based chemotherapy (PCV [procarbazine, CCNU, vincristine]/BCNU [bis-chloronitrosourea]) in the treatment of recurrent WHO astrocytic tumours grades III and IV (anaplastic astrocytoma and glioblastoma multiforme)

### Acronym
BR12

### Study objectives
BR12 is a randomised trial which compares standard PCV chemotherapy with two temozolomide schedules in patients with histologically confirmed recurrent World Health Organisation (WHO) Grade III or IV astrocytic tumour who have had primary radiotherapy (but no prior chemotherapy).

More details can be found at: http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=7

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
No ethics information required at time of registration.

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Astrocytic tumours (anaplastic astrocytoma and glioblastoma multiforme)

### Interventions
1. Temozolomide according to one of two schedules:
a. Temozolomide, 200 mg/m^2 orally (po) days one to five
b. Temozolomide, 100 mg/m^2 po days one to 21
2. PCV chemotherapy (CCNU 100 mg/m^2 po day one, Procarbazine 100 mg/m^2 po days one to ten, Vincristine 1.5 mg/m^2 (max 2 mg) intravenous (iv) day one)

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Procarbazine, CCNU, vincristine, bis-chloronitrosourea, temozolomide

### Primary outcome measure
The primary objective of the trial is to evaluate, in a group of patients representative of those who are considered for chemotherapy outside of trials, the potential benefit of temozolomide compared to PCV with respect to survival in patients with recurrent malignant glioma.

### Secondary outcome measures
In addition, the treatments will be compared with respect to the following secondary outcome measures: survival free from progression (confirmed radiologically), and health-related quality of life. A further objective is to evaluate the comparative efficacy (progression-free survival) and toxicity of the two different temozolomide schedules.

### Overall study start date
03/01/2003

### Completion date
01/01/2008

## Eligibility

### Key inclusion criteria
1. Patients with histologically verified anaplastic astrocytoma, glioblastoma multiforme or gliosarcoma (WHO grade III/IV at diagnosis or relapse) who have undergone primary treatment

which must include radiotherapy
2. Evidence of first progression confirmed by imaging (Computed Tomography [CT] or Magnetic Resonance Imaging [MRI])
3. Evaluable enhancing recurrent tumour on contrast enhanced MRI/CT scan (within 14 days prior to start of treatment)
4. Life expectancy more than or equal to one month (based on age, performance status)
5. Considered fit for chemotherapy
6. More than or equal to two months from completion of radiotherapy
7. No previous chemotherapy, radiosurgery or interstitial radiotherapy (brachytherapy) for glioma; debulking surgery on relapse is permissible
8. Adequate hepatic, renal and haematological function (within 14 days prior to entry). Absolute Neutrophil Count (ANC) more than or equal to 1500/mm^3; platelet count more than or equal to 100,000/mm^3; Blood Urea Nitrogen (BUN) and serum creatinine less than 1.5 x Upper Limit of local laboratory Normal range (ULN); Total and direct serum bilirubin less than 1.5 x ULN; Serum Glutamic-Oxaloacetic Transaminase (SGOT) or Serum Glutamic Pyruvic Transaminase (SGPT) less than 3 x ULN; Alkaline phosphatase less than 2 x ULN
9. Written informed consent given

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
500

### Key exclusion criteria
Age less than 18 years
WHO performance status grade 4
Previous recurrence
Pregnancy, breast feeding, patient or partner not using adequate contraception
Concomitant serious illness
Patients diagnosed with Oligodendroglioma

### Date of first enrolment
03/01/2003

### Date of final enrolment
01/01/2008

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**MRC Clinical Trials Unit**
London
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# Sponsor information

**Organisation**
Medical Research Council (MRC) (UK)

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**Sponsor type**
Research council

**Website**
http://www.mrc.ac.uk

# Funder(s)

**Funder type**
Research council

**Funder Name**
Medical Research Council (UK)

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Plain English results | | | | No | Yes |
| Results article | results | 20/10/2010 | | Yes | No |