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	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
21/09/2000		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/09/2000	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
05/10/2018	Cancer			

# 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

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

### Clinical Trials Information System (CTIS)

2005-004622-24

### ClinicalTrials.gov (NCT)

NCT00052455

#### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)

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.

### Key secondary outcome(s))

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.

### 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**

# Healthy volunteers allowed

No

### Age group

Adult

#### Sex

All

### 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

**United Kingdom** 

England

# Study participating centre MRC Clinical Trials Unit London

United Kingdom NW1 2DA

# Sponsor information

## Organisation

Medical Research Council (MRC) (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**

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?
Results article	results	20/10/2010		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes