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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
United Kingdom
NW1 2DA

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