

# A randomised trial of adjuvant procarbazine, CCNU, vincristine chemotherapy in patients with highly anaplastic oligodendroglioma (BR11) - EORTC

<b>Submission date</b> 06/04/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/04/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/10/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Simon Clawson

**Contact details**  
MRC Clinical Trials Unit  
222 Euston Road  
London  
United Kingdom  
NW1 2DA  
-  
none@provided.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**  
NCT00002840

## Secondary identifying numbers

S200/1233 BR11

# Study information

## Scientific Title

A randomised trial of adjuvant procarbazine, CCNU, vincristine chemotherapy in patients with highly anaplastic oligodendroglioma (BR11) - EORTC

## Acronym

BR11

## Study objectives

To determine the efficacy and safety of adjuvant PCV chemotherapy in patients with anaplastic oligodendroglioma following surgery and radiation therapy.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

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

Brain tumour

## Interventions

1. One group has surgery plus chemotheapy plus PCV chemotherapy (6 cycles of every 6 weeks, CCNU 110 mg/m<sup>2</sup> po day 1; Procarbazine 60 mg/m<sup>2</sup> po days 8-21; Vincristine 1.4 mg/m<sup>2</sup> iv on day 8 and day 29)
2. The other group has surgery and radiotherapy only

**Intervention Type**

Drug

**Phase**

Phase III

**Drug/device/biological/vaccine name(s)**

lomustine, procarbazine, vincristine

**Primary outcome measure**

Survival

**Secondary outcome measures**

Progression-free survival, quality of life including neurotoxicity and neuropsychological impairments

**Overall study start date**

01/01/1999

**Completion date**

01/03/2002

**Eligibility****Key inclusion criteria**

1. Newly diagnosed anaplastic oligodendroglioma, or oligoastrocytoma (with 25% or more oligodendral elements); including patients treated with surgery only for a low grade oligoastrocytoma or oligodendroglioma who are diagnosed with anaplastic tumour at the time of recurrence
2. At least three of five histologic anaplastic features: high cellularity, nuclear abnormalities, mitoses, endothelial abnormalities and necrosis, as diagnosed by the local pathologist

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

350

**Total final enrolment**

368

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/01/1999

**Date of final enrolment**

01/03/2002

## Locations

**Countries of recruitment**

Austria

Belgium

England

Finland

France

Germany

Hungary

Italy

Netherlands

Portugal

Sweden

Switzerland

United Kingdom

**Study participating centre**

**MRC Clinical Trials Unit**

London

United Kingdom

NW1 2DA

## Sponsor information

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

20 Park Crescent  
London  
United Kingdom  
W1B 1AL  
+44 (0)20 7636 5422  
clinical.trial@headoffice.mrc.ac.uk

**Sponsor type**

Research council

**Website**

<http://www.mrc.ac.uk>

**Funder(s)****Funder type**

Research council

**Funder Name**

Medical Research Council (MRC) (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**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	20/06/2006		Yes	No
<a href="#">Results article</a>	results	20/12/2007		Yes	No
<a href="#">Results article</a>	results	20/12/2007		Yes	No
<a href="#">Results article</a>	results	01/12/2009		Yes	No
<a href="#">Plain English results</a>		05/05/2010	29/10/2021	No	Yes