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

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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^2 po day 1; Procarbazine 60 mg/m^2 po days 8-21; Vincristine 1.4 mg/m^2 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
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Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
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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 (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?
Results article	results	20/06/2006		Yes	No
Results article	results	20/12/2007		Yes	No
Results article	results	20/12/2007		Yes	No
Results article	results	01/12/2009		Yes	No
Plain English results		05/05/2010	29/10/2021	No	Yes