

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
Registration date 06/04/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/10/2021	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00002840

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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/m² po day 1; Procarbazine 60 mg/m² po days 8-21; Vincristine 1.4 mg/m² 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(s)

Survival

Key secondary outcome(s)

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

Completion date

01/03/2002

Eligibility

Key inclusion criteria

1. Newly diagnosed anaplastic oligodendroglioma, or oligoastrocytoma (with 25% or more oligodendroglial 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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Austria

Belgium

Finland

France

Germany

Hungary

Italy

Netherlands

Portugal

Sweden

Switzerland

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 (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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