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A study of radiotherapy with or without chemotherapy in primary central nervous system (CNS) lymphoma

Submission date 28/02/2001	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/02/2001	**Overall study status** Stopped	
Last Edited 29/07/2009	**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

Secondary identifying numbers
BR06

Study information

Scientific Title

Study objectives
To evaluate the effect of CHOP chemotherapy on event-free and overall survival.

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

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

Interventions
Group 1: radiotherapy alone (54 Gy total dose in 27 fractions)
Group 2: radiotherapy as above, followed after 4 weeks by six cycles of CHOP chemotherapy given at 3-week intervals (cyclophosphamide 750 mg/m^2 iv, adriamycin 50 mg/m^2 iv, vincristine 1.4 mg/m^2 iv (max 2 mg) and prednisolone (20 mg po tds for 5 days)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
CHOP chemotherapy

Primary outcome measure

Survival.

Secondary outcome measures
Event-free survival.

Overall study start date
01/11/1988

Completion date
01/10/1995

Reason abandoned (if study stopped)
Slow accrual

Eligibility

Key inclusion criteria
1. Pathologically proven primary cerebral lymphoma
2. Aged 18-75
3. No previous radiotherapy or chemotherapy
4. Adequate neurological, physical and mental function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Not Specified

Target number of participants
Target: 90, accrued: 53

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/1988

Date of final enrolment
01/10/1995

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)

Sponsor details
20 Park Crescent
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W1B 1AL
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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

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 in: GM Mead, NM Bleehen, A Gregor, J Bullimore, R Rampling, JT Roberts, M Glaser, P Lantos, JW Ironside, TH Moss, M Brada, JB Whaley and SP Stenning for the MRC Brain Tumour Working Party (). A Medical Research Council Randomised Trial in patients with primary cerebral non-Hodgkin lymphoma. Cancer 89(6): 1359-1370	15/09/2000		Yes	No