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A randomised phase III trial of focal fractionated conformal stereotactic boost following conventional radiotherapy of high grade gliomas

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 20/09/2017	**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
NCT00003916

Secondary identifying numbers
E164/8 (BR10)

Study information

Scientific Title
A randomised phase III trial of focal fractionated conformal stereotactic boost following conventional radiotherapy of high grade gliomas

Study objectives
To determine the effect of a stereotactic boost of radiotherapy on the survival time of patients with high-grade gliomas.

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
The trial is designed to randomise patients between two treatment arms:
1. Conventional radiotherapy
2. Conventional radiotherapy plus a stereotactic boost

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Survival and quality of life.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/1999

Completion date
07/12/2001

Eligibility

Key inclusion criteria
1. Histologically confirmed gliomas World Health Organisation (WHO) III/IV, no previous histology of low grade tumours WHO I/II
2. Tumour volumes less than 4.0 cm
3. No tumours in brain stem or infratentorial location, no multifocal gliomas
4. Ability to treat tumour safely by stereotactic radiotherapy
5. Eastern Cooperative Oncology Group (ECOG)/World Health Organisation (WHO) performance status 0-2
6. Patient able to tolerate full course of conventional radiotherapy
7. Prior neurosurgery within 6 weeks of randomisation
8. Aged greater than 18 and less than 65 years
9. Informed consent
10. No prior chemo- or radiotherapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Not Specified

Target number of participants
605

Key exclusion criteria
Not provided at time of registration

Date of first enrolment

01/04/1999

Date of final enrolment
07/12/2001

Locations

Countries of recruitment
Australia

England

France

Germany

Netherlands

Spain

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
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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?
Other publications	article	01/04/1999		Yes	No
Results article	results	01/08/2008		Yes	No