

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
Registration date 06/04/2000	Overall study status Completed	☐ Protocol
Last Edited 20/09/2017	Condition category Cancer	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Miss Sally Stenning

Contact details

MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

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ss@ctu.mrc.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00003916

Protocol serial number

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

Study type(s)

Treatment

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(s)

Survival and quality of life.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

Not Specified

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**

United Kingdom

England

Australia

France

Germany

Netherlands

Spain

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

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	01/08/2008		Yes	No
Other publications	article	01/04/1999		Yes	No