A study of adjuvant chemotherapy for malignant glioma

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/02/2001		Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/02/2001	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
12/04/2012	Cancer			

Plain English summary of protocol

http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=101

Contact information

Type(s)

Scientific

Contact name

Dr Hannah Brooks

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers BR05

Study information

Scientific Title

Study objectives

To assess whether the addition of chemotherapy to a standard radiotherapy regime influences the survival of adult patients with malignant glioma (astrocytomas grades 3 & 4) and to assess the ability of in vitro chemosensitivity testing to identify patients with a better prognosis.

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

- 1. One group receives chemotherapy added to a standard radiotherapy regimen
- 2. The other group receives none

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Chemotherapy

Primary outcome measure

Survival time

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/1988

Completion date

30/06/1996

Eligibility

Key inclusion criteria

- 1. Age 18-69
- 2. No previous treatment except surgery, corticosteroids, anticonvulsants or diuretics
- 3. Entry within 6 weeks of surgery
- 4. Other malignancies
- 5. Fitness for treatment

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

69 Years

Sex

Both

Target number of participants

600

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/1988

Date of final enrolment

30/06/1996

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 London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

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

LocationUnited 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	15/01/2001		Yes	No