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A randomised study of two schedules of radiotherapy or chemotherapy in elderly patients with high grade glioma

Submission date 12/02/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/03/2010	**Overall study status** Completed	
Last Edited 30/10/2012	**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
N/A

Study information

Scientific Title
A multicentre randomised active controlled study comparing two schedules of radiotherapy or chemotherapy in elderly patients with high grade glioma

Acronym
Temodal elderly

Study objectives
To compare conventional radiotherapy (RT) (2 Gy up to 60 Gy) to short term RT (3.4 Gy up to 34 Gy) or chemotherapy alone after surgery or biopsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Linköping Ethics Committee approved in April 1999 (ref: Dnr 99086)

Study design
Multicentre open label randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Malignant glioma, grade 3-4 or 4

Interventions
Patients were randomised to either
1. Standard RT (60 Gy in 2 Gy fractions over 6 weeks)
2. Hypofractionated RT (34 Gy in 3,4 Gy fractions over 2 weeks)
3. 6 cycles of chemotherapy with TMZ (200 mg/m2 day 1-5 every 28 days)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Temozolomide (Temodal®) (TMZ)

Primary outcome measure
1. Survival

Secondary outcome measures
1. Quality of Life
2. Symptom control
3. Safety
4. Health resource utilization

Overall study start date
01/02/2000

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Age > 60
2. Performance Status (PS) 0-2 according to the WHO definition. Patients with a general condition corresponding to WHO 0-2, but due to physical handicap are graded as PS 3 or 4 can also be included.
3. Patients with histologically/cytologically confirmed glioma grade 3-4 or 4
4. Expected to tolerate all three treatment options
5. Life expectancy of at least 3 months
6. General organ function allowing chemotherapy as indicated by:
6.1. Neutrophiles > 1.5 x 109/l
6.2. Platelets > 100 x 109/l
6.3. Haemoglobin > 10 g/dl (100g/l)
6.4. Serum creatinine and bilirubin < 1.5 times upper normal limit
6.5. Aspartate Aminotransferase (ASAT), alanine Aminotransferase (ALAT) < 3 times upper normal limit
7. No other medical condition likely to interfere with treatment or the assessment of its efficacy
8. Patient is on the lowest steroid dose, which gives optimal functional improvement
9. Written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned 480, stopped at 342

Key exclusion criteria
1. Patients with other primary cancer, with the exception of radically treated squamous or basal cell carcinoma of the skin or other curatively treated malignancy without relapse 2 years after diagnosis
2. PS WHO grade 3-4, except for patients with a general condition corresponding to WHO 0-2, but due to physical handicap are graded as PS 3 or 4
3. Any other medical condition which, in the view of the investigator, is a contraindication to inclusion in the study
4. Chemotherapy, biological therapy, radiotherapy or immunotherapy given previously for brain tumour or within 3 years for other malignancy
5. Radiotherapy to the head, which would interfere with giving radiotherapy treatment for brain tumour

Date of first enrolment
01/02/2000

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Austria

Denmark

France

Norway

Sweden

Switzerland

Türkiye

Study participating centre
Unit of Advanced Palliative Home Care
Linköping
Sweden
581 85

Sponsor information

Organisation
Nordic Clinical Brain Tumor Study group (Sweden)

Sponsor details
c/o Prof Roger Henriksson
Radiumhemmet
Karolinska Hospital in Solna
Stockholm
Sweden
17176

Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Nordic Clinical Brain Tumor Study group (Sweden)

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	01/09/2012		Yes	No