

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

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| Submission date 12/02/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 03/03/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 30/10/2012 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Annika Malmström

Contact details

Unit of Advanced Palliative Home Care
(Linköpings Avancerad Hemsjukvård [LAH])
Linköping Regional Hospital (Regionsjukhuset i Linköping)
Linköping
Sweden
581 85

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. Neutrophils > $1.5 \times 10^9/l$
 - 6.2. Platelets > $100 \times 10^9/l$
 - 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 |