

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

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

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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/m<sup>2</sup> day 1-5 every 28 days)

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Temozolomide (Temodal®) (TMZ)

**Primary outcome(s)**

1. Survival

**Key secondary outcome(s)**

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

**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

### Healthy volunteers allowed

No

### Age group

Senior

### Sex

All

### 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)

**Funder(s)****Funder type**

Other

**Funder Name**

Nordic Clinical Brain Tumor Study group (Sweden)

**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?
<a href="#">Results article</a>	results	01/09/2012		Yes	No