

# A randomised study of radiotherapy and concomitant Temodal® (temozolomide) or neoadjuvant chemotherapy followed by radiotherapy and concomitant Temodal® in patients with high grade glioma

<b>Submission date</b> 25/08/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/09/2011	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

A multicentre, phase III, randomised controlled trial of radiotherapy and concomitant Temodal® (temozolomide) or neoadjuvant chemotherapy followed by radiotherapy and concomitant Temodal® in patients with high grade glioma

**Acronym**

Temodal, neoadjuvant trial

**Study objectives**

To compare the efficacy and safety of conventional and concomitant Temodal® in patients with anaplastic astrocytoma (AA) or glioblastoma multiforme (GBM).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The local ethics committee (Ethic comité Umeå) approved in August 2008 (ref: 02-317)

**Study design**

Multicentre prospective phase III randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Grade III (anaplastic astrocytoma) or grade IV (glioblastoma multiforme) tumours

**Interventions**

Patients will be randomised to receive either

1. Conventional radiotherapy and temozolomide:

60 Gy radiotherapy is administered in 2 Gy fractions over 6 weeks, concomitantly with daily doses of temozolomide 75 mg/m<sup>2</sup>

2. Neoadjuvant temozolomide 2-3 cycles followed by radiotherapy

3 cycles of temozolomide dosage 200 mg/m<sup>2</sup> days 1-5 in a 28 days schedule, with radiologic evaluation before start of treatment and after 2 cycles. If progression is noted cycle 3 is omitted. Radiotherapy is administered in the same way as for the standard treatment arm.

Follow up for both treatment arms is 1 and 3 months after end of treatment.

**Intervention Type**

Other

**Phase**

Phase III

**Primary outcome(s)**

Overall survival

**Key secondary outcome(s))**

1. Safety, all adverse events are collected
2. Quality of Life (QoL), evaluated by the EORTC QLQ-30 before start of treatment, then 12 and 24 months after start of treatment.

**Completion date**

21/05/2009

## Eligibility

**Key inclusion criteria**

1. Written informed consent
2. Histologically proven astrocytic glioma (grade III: AA or grade IV: GBM)
3. Age 18 - 60 years
4. Performance status WHO 0-2
5. Life expectancy > 3 months
6. Normal organ function, except if abnormal due to tumour involvement as indicated by:
  - 6.1. Platelet count (TPK) <  $100 \times 10^9/L$
  - 6.2. Haemoglobin (Hb) > 90 g/L
  - 6.3. Neutrophils: <  $1.5 \times 10^3/mm^3$  or LPK <  $3.0 \times 10^9/L$
  - 6.4. Serum creatinine and bilirubin < 1.5 times the upper limit of normal (ULN)
  - 6.5. Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) < 3 x ULN
7. Men and women of child bearing potential must be using adequate contraception

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Key exclusion criteria**

1. Prior chemotherapy or radiotherapy for malignant glioma
2. Any other active malignancies within the last 5 years, except adequately treated basal or squamous cell carcinoma of the skin or carcinoma in situ
3. Pregnancy or breast feeding
4. Any condition (medical, social, psychological) which would prevent adequate information and follow up

**Date of first enrolment**

13/01/2003

**Date of final enrolment**

21/05/2009

## Locations

## Countries of recruitment

Denmark

Finland

Norway

Sweden

## Study participating centre

Radiumhemmet

Stockholm

Sweden

171 74

## Sponsor information

### Organisation

Nordic Clinical Brain Tumour Study Group (Sweden)

## Funder(s)

### Funder type

Research organisation

### Funder Name

Nordic Clinical Brain Tumour 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="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes

