

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

Submission date 25/08/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/09/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/09/2011	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Written and oral

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/m²

2. Neoadjuvant temozolomide 2-3 cycles followed by radiotherapy

3 cycles of temozolomide dosage 200 mg/m² 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 measure

Overall survival

Secondary outcome measures

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.

Overall study start date

13/01/2003

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 x 10⁹/L
 - 6.2. Haemoglobin (Hb) > 90 g/L
 - 6.3. Neutrophils: < 1.5 x 10³/mm³ or LPK < 3.0 x 10⁹/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

Age group

Not Specified

Sex

Not Specified

Target number of participants

Planned 322, stopped at 143

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)

Sponsor details

c/o Prof Roger Henriksson

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171 74

Sponsor type

Research organisation

Funder(s)

Funder type

Research organisation

Funder Name

Nordic Clinical Brain Tumour 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