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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	[ ] Prospectively registered [ ] Protocol
Registration date 23/09/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 07/09/2011	**Condition category** Cancer	[ ] Individual participant data [ ] 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 comitteé Umeà) 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 ond 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 10^9/L
6.2. Haemoglobin (Hb) > 90 g/L
6.3. Neutrophils: < 1.5 x 10^3/mm3 or LPK < 3.0 x 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

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
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Sponsor information

Organisation
Nordic Clinical Brain Tumour Study Group (Sweden)

Sponsor details
c/o Prof Roger Henriksson
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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