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Temozolomide in children with recurrent or refractory central nervous system (CNS) tumours [Temozolomide bij kinderen met een gerecidiveerde of refractaire centraal zenuwstelsel tumor]

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/06/2008	Cancer	[ ] 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
NTR227

Study information

Scientific Title

Acronym
TMZ studie

Study objectives
Administration of a higher cumulative dose of temozolomide leads to a higher response rate in patients with recurrent primitive neuro-ectodermal tumours and recurrent high grade gliomas of the central nervous system (CNS), while this treatment does not lead to more side effects.

Please note that as of 24/06/2008 more details on the sources of funding have been added to this record (i.e., funding now confirmed). This can be seen below in the sources of funding section.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, multicentre, active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Glioma high grade, primitive neuroectodermal tumour (PNET)

Interventions
Two different dose schedules of temozolomide are compared:
1. In the standard arm 200 mg/m^2/dag is administered 5 days per 28 days
2. In the experimental arm 150 mg/m^2 is administered 2 x 7 dagen (day 0 - 6 and day 14 - 20) per 28 days

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
Difference in magnetic resonance imaging (MRI) response after 12 weeks between the two arms.

Key secondary outcome(s))
Difference in side effects after 12 weeks between the two arms.

Completion date
01/01/2009

Eligibility

Key inclusion criteria
1. Aged 3 - 18 years
2. Pathology: primitive neuroectodermal tumour (PNET)/high grade glioma
3. Measurable tumour
4. Lansky score greater than 50%
5. Expected life span of 12 weeks or more
6. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
Non-conformation to inclusion criteria

Date of first enrolment
01/01/2004

Date of final enrolment
01/01/2009

Locations

Countries of recruitment

Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Dutch Childhood Oncology Group (Stichting Kinder Oncologie [SKION]) (The Netherlands)

ROR
https://ror.org/01zs6bp63

Funder(s)

Funder type
Industry

Funder Name
Added as of 24/06/2008:

Funder Name
Schering-Plough B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration