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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 20/12/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 20/12/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 24/06/2008	**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

Contact name
Dr R.E. Reddingius

Contact details
Erasmus Medical Center
Sophia Children's Hospital
Rotterdam
Netherlands
3015 GJ
+31 (0)10 463 6363
r.reddingius@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Difference in side effects after 12 weeks between the two arms.

Overall study start date
01/01/2004

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

Age group
Child

Lower age limit
3 Years

Upper age limit
18 Years

Sex

Both

Target number of participants
54

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)

Sponsor details
Leyweg 299
Den Haag
Netherlands
2545 CJ
+31 (0)70 367 4545
info@skion.nl

Sponsor type
Research organisation

Website
http://www.skion.nl/

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

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