Temozolomide in children with recurrent or refractory CNS tumors.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28755

Source
Nationaal Trial Register

Brief title
TMZ studie

Health condition

recurrent primitive neuro ectodermal tumors and recurrent high grade gliomas of the CNS in children.

Sponsors and support

Primary sponsor: SKION (Stichting Kinder Oncologie); Schering Plough
Source(s) of monetary or material Support: n/

Intervention

Outcome measures

Primary outcome

Difference in MRI respons after 12 weeks between the 2 arms.

Secondary outcome

Difference in side effects after 12 weeks between the 2 arms.

Study description

Background summary

For childen with recurrent or refractory primitive neuro ectodermal tumor (PNET) or high grade glioma of the brain, for whom there is no curative treatment, it is important to preserve quality of life as long as possible without causing significant side effects.
Temozolomide seems to be an interesting drug because it can be administered orally and has little side effects.
Not much information however is available about the administration of this drug in children.
In this protocol two different dose schedules of temozolomide are compared:
- In the standard arm 200 mg/m2/dag is administered 5 days per 28 days.
- In the experimentel arm 150 mg/m2 is administered 2 x 7 dagen (day 0-6 and day 14-20) per 28 days.
Effectivity and side effects are studied. The effectivity is studied by looking at radiological respons after 3 cycles.

Study objective

Administration of a higher cumulative dose of temozolomide leads to a higher respons rate in patients with recurrent primitive neuro ectodermal tumors and recurrent high grade gliomas of the CNS, while this treatment does not lead to more side effects.

Intervention

Two different dose schedules of temozolomide are compared:

- In the standard arm 200 mg/m2/dag is administered 5 days per 28 days.

- In the experimental arm 150 mg/m2 is administered 2 x 7 dagen (day 0-6 and day 14-20) per 28 days.

Contacts

Public
Erasmus Medical Center, Sophia Children's Hospital,
Dr. Molewaterplein 60
R.E. Reddingius
Dr. Molewaterplein 60

Rotterdam 3015 GJ
The Netherlands
+31 (0)10 4636363
Scientific
Erasmus Medical Center, Sophia Children's Hospital,
Dr. Molewaterplein 60
R.E. Reddingius
Dr. Molewaterplein 60
Rotterdam 3015 GJ
The Netherlands
+31 (0)10 4636363

Eligibility criteria

Inclusion criteria

1. Age 3-18;

2. Pathology: PNET/high grade glioma
measurable tumor;

3. Lansky score > 50 %;

4. Expected life span of 12 weeks or more;
5. Informed consent.

Exclusion criteria

Non conformation to inclusion criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2004
Enrollment:	54
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL190
NTR-old	NTR227
Other	: N/A
ISRCTN	ISRCTN16192422

Study results

Summary results

N/A