Determining the tumor uptake of labelled bevacizumab in children with high grade or diffuse intrinsic pontine glioma on PET scans.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27519

Source
Nationaal Trial Register

Brief title
89Zr-Bmab PET in pHGG & DIPG

Health condition

Diffuse intrinsic pontine glioma
Pediatric high grade glioma
Malignant glioma
Hooggradig glioom
Ponsglioom

Sponsors and support

Primary sponsor: VU University Medical Center

Intervention

Outcome measures

Primary outcome

VEGF-expression measured by Standard Uptake Values of 89Zr-Bevacizumab in pHGG and DIPG.

Secondary outcome

1. Optimal moment of scanning obtained by five patients with positive 89Zr-bevacizumab uptake;

2. Body biodistribution and dosimetry of 89Zr-bevacizumab.

Study description

Background summary

Paediatric high grade gliomas (pHGG) including diffuse intrinsic pontine gliomas (DIPG) have a poor prognosis. PET imaging with labelled antibodies enables drug distribution investigations and non-invasive target expression studies. pHGG and DIPG highly express vascular endothelial growth factor (VEGF) on RNA level, which is involved in mitogenic, angiogenic, and permeability enhancing processes. Monoclonal antibody bevacizumab inhibits VEGF-A and showed efficacy in adult glioma and to a lesser extend in pHGG. Bevacizumab is labelled to Zirconium-89, a positron emitter with a long half-time which is preferable because of its safety, purity and stable binding to its antibody and relatively low costs. In adults, 89Zr-bevacizumab could be used safely in humans and was shown to visualise targets precisely. In this study, bevacizumab is administered in a microdose at 1/100th of the therapeutic dose in pHGG and DIPG. PET scans are performed at 1, 72 and 144 hours post-injection. We expect that PET-imaging of 89Zr-bevacizumab may help to select patients more likely to respond to bevacizumab therapy.

Study objective

Is there VEGF-expression in DIPG & HGG measured by the tumor uptake of Zr-bevacizumab?

Study design

89Zr-bevacizumab is injected and PET scans are performed at 1, 72 and 144 hours post-injection.

Intervention

This is a diagnostic PET study. The labelled antibody is 89Zr-Bevacizumab.

Contacts

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Eligibility criteria

Inclusion criteria

1. DIPG (MRI confirmed, biopsy not required) de novo;

2. De novo biopsy proven HGG patients with minimal residual tumor of 0.5 mm in each dimension or;

3. pHGG & DIPG patients with progressive disease after radiotherapy;

4. Age between 4 and 18 years;

5. Able to lay down quiet for 30 minutes.

Exclusion criteria

1. Chemotherapy or radiotherapy in the past two weeks;

2. Previous administration of bevacizumab or another anti-VEGF drug;

3. Known hypersensitivity against humanized monoclonal antibodies;

4. Neurofibromatosis type I.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2011
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-07-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38105
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3370
NTR-old	NTR3518
CCMO	NL34922.000.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38105

Study results

Summary results

Jansen MH, van Vuurden DG, Vandertop WP, Kaspers GJ. Diffuse intrinsic pontine gliomas: A systematic update on clinical trials and biology. Cancer Treat Rev. 2012;38:27-35

Van Dongen GA, Visser GW, Lub-de Hooge MN, de Vries EG, Perk LR. Immuno-PET: a navigator in monoclonal antibody development and applications. Oncologist 2007:12: 1379-1389.