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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27519

Bron
NTR

Verkorte titel
89Zr-Bmab PET in pHGG & DIPG

Aandoening

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

Ondersteuning

Primaire sponsor: VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38105
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.