Pilot to validate in vivo 2-HG MR spectroscopy in low grade gliomas

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We expect that patients with a IDH mutation demonstrate an increase in 2-HG on MR spectroscopy. We also expect a positive correlation between in vivo 2-HG on MR spectroscopy and ex vivo concentration in tissue.

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24067

Bron
Nationaal Trial Register

Aandoening

2-HG
MRI
Spectroscopy
Low grade glioma
IDH

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Groningen
Overige ondersteuning: Universitair Medisch Centrum Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint is the correlation between the presence of the IDH mutation and a 2-HG

peak on MR spectroscopy (binary variables). Also primary endpoint is the correlation between the concentration of 2-HG on in vivo MR spectroscopy and ex vivo in the tissue, uitgedrukt in mmol/mg (continue variabelen).

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study: Low grade gliomas are brain tumors that occurs mainly in young adults. The mean survival is about 10 years. The tumor might be difficult to resect if located near an important brain area. Treatment is best done using radiotherapy and chemotherapy in such cases. However, the diagnosis should be established with certainty with a brain biopsy. However, a biopsy induces the risk of brain damage. Unfortunately, a brain biopsy is the only way to establish the diagnosis with certainty currently.

An alternative seems possible. Low grade gliomas have a IDH gene mutation. This mutation results in the production of 2-hydroxyglutarate (2-HG). 2-HG seems to be measurable on a specific MRI sequence, MR spectroscopy.

The current pilot study will investigate if this IDH gene mutation indeed result in the presence of 2-HG on MRI. We also validate if the concentration measured on MRI correlate with the concentration measured in the tissue.

If indeed positive, we are able to set-up an follow-up study (not part of the current protocol) to see if the 2-HG MR scan could replace a brain biopsy in patient with a low grade gliomas.

Objective of the study: Primary goal is to investigate if the 2-HG peak on in vivo MR spectroscopy correlates with the ex vivo IDH mutation and 2-HG concentration in patients with a low grade gliomas.

Study design: A pilot study to validate 2-HG spectroscopy in patients with a low grade glioma.

Study population: Patients with a low grade glioma ≥ 18 years old that a planned to undergo surgery (N=10).

Primary study parameters/outcome of the study: Primary endpoint is firstly the correlation between the presence of the IDH mutation and the presence of the 2-HG peak on MR spectroscopy (binary variables). Also primary endpoint is the correlation between the concentration of 2-HG on in vivo MR spectroscopy and ex vivo in the tissue in mmol/mg (continue variables).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable): Participants will not have and advantages from participation in the research. The standard clinical diagnostic and therapeutic procedures will not change. Participants will have no additional costs and will not receive any financial compensation. The

discomfort is that they will have to lay down 15 minutes longer in the already planned MRI scan. The MRI will last 55 minutes instead of 40 minutes.

Doel van het onderzoek

We expect that patients with a IDH mutation demonstrate an increase in 2-HG on MR spectroscopy. We also expect a positive correlation between in vivo 2-HG on MR spectroscopy and ex vivo concentration in tissue.

Onderzoeksopzet

pre-operative MR Spectroscopy. 2-HG tissue concentration measurement post-operative ex-vivo.

Onderzoeksproduct en/of interventie

MR spectroscopy for 2-HG.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with a low grade glioma ≥ 18 years that are planned to undergo surgery

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients with recent cerebral radiotherapy or operation (<3 months).

- Age <18 years.

- General contra-indications for MRI (non compatible material , pregnancy or claustrophobia)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-03-2018
Aantal proefpersonen:	10
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46642
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6798
NTR-old	NTR6984
CCMO	NL64707.042.18
OMON	NL-OMON46642

Resultaten