Value of 7 Tesla in gliomas

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Compared to the lower field MR systems, 7 Tesla MRI has an additional role in identifying tumor characteristics.

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

Samenvatting

ID

NL-OMON24352

Bron
NTR

Verkorte titel
Glioma7T

Aandoening

High grade and low grade glioma

Ondersteuning

Primaire sponsor: Medical Delta
Overige ondersteuning: Medical Delta

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To identify and describe radiological tumor characteristics of glioma on 7 Tesla MRI (3DT1, 3DT2, TOF,
FLAIR, T2*, MRS, CEST) and 1.5/3 T MRI (T1W1 with and without gadolinium, T2W1, FLAIR, perfusion (DSC), DWI).

Toelichting onderzoek

Achtergrond van het onderzoek

The 7 Tesla MRI is an ultrahigh field MRI system and shows great potential for the use in clinical practice. In patients with glioma the 7 Tesla MRI may have an additional role in monitoring
treatment response and tumor progression, since at lower field MRI systems it is still difficult to
differentiate between radionecrosis and tumor recurrence. In different neurological diseases it has
already been proven that the 7 Tesla MRI provides additional information compared to lower field MRI
systems.
The primary aim of this study is to identify and describe radiological tumor characteristics in glioma on 7 Tesla MRI compared to standard 1.5/3 Tesla MRI. The secondary aim is to develop an MRI
scan protocol for gliomas on 7 Tesla MRI.
The study "value of 7 Tesla in glioma" is across-sectional pilot study. For this pilot study we aim to include 25 glioma patients.
The study population consists of adult patients with a histologically proven or highly suspected glioma. With the standard imaging protocol of the 1.5/3 Tesla MRI (T1W1 with and without gadolinium, T2W1, FLAIR, perfusion(DSC), DWI) and a newly developed 7 Tesla
MRI scan protocol (3DT1, 3DT2, TOF, FLAIR T2*, MRS, CEST) we assess radiological tumor characteristics and the effects of antitumor treatment.

Doel van het onderzoek

Compared to the lower field MR systems, 7 Tesla MRI has an additional role in identifying tumor characteristics.

Onderzoeksopzet

The work towards the secondary outcome objective is initiated at the start of the study. The development for the most optimal protocol is performed prior starting scanning patients and its feasibility is confirmed while the study is ongoing. For this, adjustments to the the 7T MRI image sequences are performed to obtain 1. high quality images, 2. a scanning protocol within reasonable time limits (60min).
The primary objective goal is reached after all patients have been included. However preliminary assessment of results will be done during inclusion. This study is also conducted at the 7T MRI, with the protocol resulting from the previous optimization step. The results obtained for this step will mostly result from medical/radiological expertise and visual evaluation.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age > 18 years old, highly suspected or histologically confirmed glioma and Karnofsky performance ≥ 70

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with contra-indications for MRI

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-02-2021
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9333
Ander register	METC Leiden – Den Haag – Delft : P18.111

Resultaten