Value of 7 Tesla in gliomas

No registrations found.

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

Summary

ID

NL-OMON24352

Source
NTR

Brief title
Glioma7T

Health condition

High grade and low grade glioma

Sponsors and support

Primary sponsor: Medical Delta
Source(s) of monetary or material Support: Medical Delta

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

To develop the most optimal scan protocol for assessment of radiological tumor characteristics of glioma
on 7 Tesla MRI.

Study description

Background summary

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.

Study objective

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

Study design

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Patients with contra-indications for MRI

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2021
Enrollment:	25
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-03-2021
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	NL9333
Other	METC Leiden – Den Haag – Delft : P18.111

Study results