

# Value of 7 Tesla in gliomas

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The primary objective is to identify and describe radiological tumor characteristics of glioma on 7 T MRI (possible relevant sequences: 3DT1, 3DT2, TOF, SWI (Duyn), FLAIR, spectroscopy and CEST) and 1.5/3 T MRI (relevant sequences: T1WI with and...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Nervous system neoplasms malignant and unspecified NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON52838

### Source

ToetsingOnline

### Brief title

Value of 7 Tesla in gliomas

### Condition

- Nervous system neoplasms malignant and unspecified NEC

### Synonym

gliomas, malignant brain tumors

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** 7 Tesla MRI, Gliomas, High field MRI

## Outcome measures

### Primary outcome

The following radiological tumor characteristics will be assessed, if possible within the 60 minutes MRI time, using the optimal imaging protocol of the 1.5/3 T MRI (T1WI with and without gadolinium, T2WI, FLAIR, SWI, perfusion(DSC), DWI) and 7 T MRI (possible relevant sequences: 3DT1, 3DT2, TOF, SWI (Duyn), FLAIR, spectroscopy and CEST).

We aim to investigate the feasibility of the following measurements:

With the 1.5/3 T MRI:

- Tumor boundaries
- Tumor vascularization
- Number and location of microbleeds
- Diffusion restriction
- Satellite lesions/multifocality of the tumor
- Susceptibility artifacts near tissue boundaries
- Magnetic field inhomogeneities )
- Tumorprogression compared to the previous MRI
- Pattern of contrast enhancing

With the 7 T MRI:

- Tumor boundaries
- Tumor vascularization
- Number and location of microbleeds
- Satellite lesions/multifocality of the tumor
- Susceptibility artifacts near tissue boundaries
- Magnetic field inhomogeneities (Signal dropout in certain brain regions)
- Metabolite information (spectroscopy: lactate, choline, lipids, myoinositol, NAA)

### **Secondary outcome**

- Duration of individual scans and the resolution needed
- Added value of each sequence in the diagnosis process
- Necessary protocol differences between operated and non-operated patients
- Robustness of sequences, especially also for providing good quality in challenging regions (near cavities, operation zone, etc.)
- Characterization of tumor (pseudo)progression

## **Study description**

### **Background summary**

For better image quality, more and more stronger magnetic fields are used. An MRI scanner with an extra high magnetic field, the 7 Tesla MRI, was installed in the LUMC in 2007. So far, the additional value of the 7 Tesla MRI in patients with glioma, compared to 1.5 or 3 Tesla MRI, is not known. The aim of this research is to recognize radiological tumor characteristics, as well as tumor and treatment response, with the 7 Tesla MRI and compare the results with the 1.5 or 3 Tesla MRI. With this research the scanning methods can be further improved and optimized. Our hypothesis is that in the MRI systems with a lower field strength, the 7 Tesla-MRI has an additional role in identifying tumor

characteristics and in the future for evaluating tumor and treatment response.

## **Study objective**

The primary objective is to identify and describe radiological tumor characteristics of glioma on 7 T MRI (possible relevant sequences: 3DT1, 3DT2, TOF, SWI (Duyn), FLAIR, spectroscopy and CEST) and 1.5/3 T MRI (relevant sequences: T1WI with and without gadolinium, T2WI, FLAIR, SWI, perfusion (DSC), DWI).

The secondary objective is to develop the most optimal scan protocol for assessment of radiological tumor characteristics for diagnosis of glioma on 7 Tesla MRI.

## **Study design**

The study \*value of 7 Tesla in glioma\* is a cross-sectional. All included patients will have their regular follow-up MRI on 1.5/3 T MRI (including T1WI with and without gadolinium, T2WI, FLAIR, SWI, perfusion(DSC), DWI) in Haaglanden Medical Center (HMC), or Leiden University Medical Center (LUMC). Within 4 weeks before or after this regular scan, a 7 T MRI in the LUMC (possible relevant sequences include: 3DT1, 3DT2, TOF, SWI (Duyn), FLAIR, spectroscopy and CEST) will be scheduled. The 7 Tesla MRI is performed without any contrast agents and the MRI-scanning will be completed within 60 minutes.

## **Study burden and risks**

It will cost the participants time to undergo the 7 Tesla MRIs. Nevertheless, the subject will be in the 7 Tesla MRI for maximal 60 minutes and the 7Tesla MRI will be performed without intravenously administered contrast agents. The participant burden is believed not to be substantial.

The ultrahigh field MRI system is widely used in research setting and since its first introduction in the 1990s no SAEs have been reported. Important temporary side-effects are vertigo, nausea and involuntary eye motion due to forces on ion currents in the semicircular loops. All individuals entering the 7 T MRI are provided adequate sound protection to reduce the acoustic noise for protecting the ears and increase patient comfort during MRI. Since magnetic metal is attracted by the static field of the 7 T MRI a safety screening questionnaire determines whether it is safe for the patient to have the MRI (see list LUMC in attachment). The Investigational Medical Device Dossier (IMDD) describes the risks analysis in more detail.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Age > 18 years
- Highly suspected or histologically confirmed glioma
- Karnofsky performance status  $\geq 70$

### Exclusion criteria

- Patients with a contra-indication for MRI (see list LUMC in attachment).

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-02-2021

Enrollment: 45

Type: Actual

## Ethics review

Approved WMO

Date: 07-05-2019

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 07-11-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 13-10-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO  
Date: 24-12-2020  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
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Approved WMO  
Date: 06-04-2022  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
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Approved WMO  
Date: 11-07-2022  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
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## 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
CCMO	NL65491.058.18