Spatial analysis and validation of glioblastoma on 7 T MRI

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Primary objective* to determine GTV in patients with an untreated GBM with 7T MRI without contrast-enhancement.Secondary objective* to compare the GTV as created based on 7T MRI to the GTV based on 3T MRI.* to determine the clinical target volume (...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON44436

Source
ToetsingOnline

Brief title
Spatial analysis and validation of glioblastoma on 7 T MRI

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
astrocytoma grade IV, Glioblastoma, malignant braintumour

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO Clinic
Source(s) of monetary or material Support: Universiteitsfonds Limburg / SWOL

Intervention

Keyword: 7 T MRI, biopsy, glioblastoma, radiotherapy

Outcome measures

Primary outcome

Main study endpoint

* The co-localisation of the GTV on the 7T MRI and 3T MRI

Secondary outcome

Secondary study endpoints

* The correspondence between glioblastoma cells found in the biopsies and

region of interest (ROI) on the 7T MRI scan.

* The co-localisation of the CTV on the 7T MRI and 3T MRI

* The co-localisation of the organs at risk (OAR) on the 7T - and 3T MRI

* The correlation between the first tumour recurrence on 3T MRI follow-up

images and ROI on the 7T MRI scan

* The quantification of tumour heterogeneity on 7T MRI and 3T MRI

* The visibility of white matter tracts on 7T MRI and 3T MRI

* Tolerability and side effects 3T MRI and 7T MRI scan with a specific MRI

questionnaire after both scans.

Study description

Background summary

Currently, patients with a glioblastoma multiforme (GBM) are treated with a combination of different therapeutic modalities including resection, concurrent chemo- and radiotherapy and adjuvant temozolomide. However, survival is still poor and most of these tumours recur within one to two years within the

previously irradiated target volume.

The radiation target volume encompasses both the contrast-enhanced lesion on T1-weighted magnetic resonance imaging (MRI), plus a 1.5 - 2 cm isotropic margin in order to include microscopic speculated growth. These margins result in a high dose to surrounding healthy appearing brain tissue. Moreover, the short progression-free survival indicates a possible geographical miss. There is a clear need for novel imaging techniques in order to better determine the degree of tumour extent at the time of treatment and to minimize the dose to healthy brain tissue.

The development of Ultra-High Field (UHF) MRI at a magnetic field strength of 7T provides an increased ability to detect, quantify and monitor tumour activity and determine post-treatment effects on the normal brain tissue as a result of a higher resolution, greater coverage and shorter scan times compared to 1.5T and 3T images. Up to now, only few investigators have examined the use of UHF MRI in patients with malignant brain tumours. These studies show its potential to assess tumour microvasculature and post-radiation effects such as microhaemorrhages.
This study analyzes the accuracy of the 7T MRI in identifying the gross tumour volume (GTV) in patients with an untreated GBM by comparing 3T MRI images to 7T images. Based on these images an extra biopsy per patient will be taken if considered safe. These biopsies will be taken from suspected regions of GBM based on 7T MRI that do not appear as such on 3T MRI. We hypothesize that with the 7T MRI the GTV can be more accurately and extensively identified when compared to the 3T MRI.

Study objective

Primary objective
* to determine GTV in patients with an untreated GBM with 7T MRI without contrast-enhancement.

Secondary objective
* to compare the GTV as created based on 7T MRI to the GTV based on 3T MRI.
* to determine the clinical target volume (CTV) in patients with a GBM with 7T MRI and compare it with the CTV based on 3T MRI.
* to assess the visibility of the organs at risk (OAR) on 7T MRI compared with 3T MRI.
* to assess tumour heterogeneity in (micro)vasculature within the GTV in patients with a GBM with 7T MRI compared with 3T MRI
* to assess the visibility of white matter tracts within the central nervous system on 7T MRI compared with 3T MRI
* to assess the tolerability and side effects of the 7T MRI compared with 3T MRI.

Study design

Prior to inclusion of patients, two healthy volunteers will be used to optimize the 7T MRI sequences.

This pilot study is a diagnostic accuracy study.
Subjects will receive a 7T MRI scan without gadolinium contrast agent prior to the biopsy. This MRI scan will be compared to the standard 3T neuro-navigation MRI scan in order to determine the exact location of ROI on the 7T MRI. If considered safe, a study biopsy will be taken from this ROI (see below).
Further treatment and follow-up will be according to standard protocol for patients with GBM.
Four to six weeks after the start of radiotherapy 2 radiation-oncologists, a resident radiation-oncology, a neuro-radiologist and a radiation technician will individually delineate the GTV, CTV and organs at risk on the 7T MR images. In order to assess intra-observer variability this delineation will be repeated after two months for both the 3T MRI and 7T MRI.

Intervention

One biopsy per patient will be taken from the ROI in addition to the standard diagnostic biopsies. Both an experienced neuro-radiologist and neuro-surgeon will assess the optimal location for the extra biopsy. The neuro-surgeon will also assess the optimal biopsy tract. The extra biopsy will only be taken if considered safe by the neuro-surgeon.

Study burden and risks

There are no immediate potential benefit for the subjects except the satisfaction to participate in this study in order to improve general knowledge.
The U.S. Food and Drug Administration considers clinical MR systems using static magnetic fields up to 8.0 Tesla as a *non-significant risk* for adult patients. Acute side effects may include vertigo, nausea, a metallic taste and phosphenes. Furthermore during the exam subjects may experience claustrophobia and palpitations.
The biopsies hold a small risk of additional permanent morbidity (3.6 * 4.7%), including haemorrhagic complications, and mortality (0 * 1.5%).

Contacts

Public
MAASTRO Clinic

Dr. Tanslaan 12

Maastricht 6229 ET
NL
Scientific
MAASTRO Clinic

Dr. Tanslaan 12
Maastricht 6229 ET
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy volunteers
Subjects with no priorly defined clinical conditions, Age 18 years and older (no maximum age), Ability to comply to study procedure, Informed consent by signing informed consent form regarding this study;Patients
Supratentorial tumour, suspected GBM on diagnostic 3T MRI, eligible for biopsy, Minimum age 18 years or older, WHO Performance scale *2, ASA class * 3, understanding of the Dutch language, ability to comply to study procedure

Exclusion criteria

Healthy volunteers
Contra-indications for 7T MRI;Patients
Recurrent tumour, tumour location deemed unfit for extra biopsies, prior radiotherapy to the skull, prior chemotherapy, eligibility for immediate debulking, contra-indications for the MRI.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2014
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	04-07-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT02062372
CCMO	NL47894.068.14