Randomized Assessment of Conventional Neuronavigation versus Intraoperative MRI for the Neurosurgical Treatment of Glioblastomas

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This study compares iMRI with cNN for the primary endpoint (percentage of residual tumor volume) and the secondary endpoints (complications, clinical functioning / quality of life, and survival).

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

Summary

ID

NL-OMON35324

Source
ToetsingOnline

Brief title
RACING-project

Condition

- Nervous system neoplasms malignant and unspecified NEC
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Synonym
glioblastoma multiforme (GBM), malignant brain tumor

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Medtronic B.V.,Medtronic Navigation

Intervention

Keyword: glioblastoma, high grade glioma, intraoperative MRI, neuronavigation

Outcome measures

Primary outcome

For each treatment group the percentage of residual tumor as visible on the

postoperative scan will be compared to tumor volume on the preoperative scan.

The main question from the RACING-project is whether iMRI helps to achieve a

lower percentage of residual tumor volume compared to cNN.

Secondary outcome

* complications

* clinical performance (WHO Performance Scale) / quality of life

* survival

Study description

Background summary

Intraoperative MRI is a technical tool to perform more effective and safer brain surgery. Current default treatment (conventional neuronavigation (cNN)) uses preoperative brain scans. During surgery several changes occur that cause "brain shift", a displacement of the brain. As a consequence, preoperative brain scans become inaccurate during surgery. iMRI can acquire a new scan during a surgical procedure to correct for this accuracy caused by brain shift.

Until now only prospective and retrospective cohort studies have been performed, but no randomized study to assess effectiveness and safety of iMRI compared to cNN. Less residual tumor volume is associated with prolonged

survival. The hypothesis is that use of iMRI leads to less residual tumor than the use of cNN.

Study objective

This study compares iMRI with cNN for the primary endpoint (percentage of residual tumor volume) and the secondary endpoints (complications, clinical functioning / quality of life, and survival).

Study design

A total of 54 patients with a brain tumor will be randomized in two treatment groups: iMRI or cNN. Both groups will have a preoperative navigation scan made within 72 hours before surgery. In both groups the neurosurgeon will operate until he/she considers tumor resection to be maximal. In the cNN-group surgery will be finished at that point. In the iMRI-group a new scan will be made after administration of an intavenous contrast agent. If this shows contrast enhancement that is interpreted by the neurosurgeon as being tumor tissue, this will be resected if the neurosurgeon thinks this is justified. Then a new scan will be made, and this "scan-resection-cycle" can be repeated until the neurosurgeon considers the resection to be maximal. In the iMRI-group surgery will be finished at that point. In both groups a new scan will be made within 48 hours after surgery. This will be used to measure postoperative tumor volume. This will be compared to the preoperative tumor volume on the preoperative navigation scan, to calculate the residual tumor volume.

Intervention

Randomization in the iMRI or cNN group, after which treatment will be given as desribed in the summary paragraph "Study Design". Before and after surgery the patient will be requested to fill in some questionnaires to address quality of life. This will be done at admission, at discharge, and 3 months after surgery.

Study burden and risks

Like explained and supported by literature references in the research protocol, there are risks related to performing brain surgery. There are no indications that this risk would be increased in the iMRI-group compared to the cNN-group (default treatment). Surgery time in the iMRI-group will be approximately 90 minutes longer compared to the cNN-group. The only burden that patients have is the questionnaires that they will be requested to fill in for three times.

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

* supratentorial brain tumor, on contrast enhanced dMRI suspected to be GBM
* indication for gross total resection (GTR) of the tumor
* age *18 years
* WHO Performance Scale * 2
* ASA class * 3
* adequate knowledge of the Dutch or French language
* informed consent

Exclusion criteria

- recurrent brain tumor

- multiple brain tumor localizations
- earlier skull radiotherapy
- earlier chemotherapy for GBM
- Chronic Kidney Disease or other renal function disorder
- known MR-contrast allergy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2010
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO Date:	23-03-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-05-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	09-08-2010
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	NCT00943007
CCMO	NL25549.068.09