Does borderzone contrast enhancement on intraoperative MRI during high grade glioma resection correlate with residual tumor?

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This study wants to evaluate on intraoperative MRI whether contrast enhancement at the borders of the resection cavity correlates with tumor tissue, and whether no contrast enhancement correlates with the absence of tumor tissue. To differentiate...

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

Summary

ID

NL-OMON31501

Source
ToetsingOnline

Brief title
Borderzone sampling

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
high grade glioma, malignant brain tumor

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

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

Intervention

Keyword: contrast enhancement, high grade glioma, intraoperative MRI

Outcome measures

Primary outcome

The relation between the shape and size of contrast enhancement on intraoperative MRI at the resection cavity border, and the presence of residual tumor tissue.

Secondary outcome

* The relation between possible contrast enhancement and contrast enhancing tissue volume on the last intraoperative MRI scan and the early diagnostic MRI scan (within 72 hours after surgery).

* Postoperative clinical condition (WHO Performance Scale).

* Survival (Kaplan Meier)

Study description

Background summary

The gold standard in brain tumor resection is to resect the contrast enhancing part as visible on pre- and postoperative MRI. During surgery several changes occur that may influence the contrast uptake by tumor tissue. The growing availability of intraoperative MRI requires a systematic evaluation to decide whether the gold standard can be applied on intraoperative MRI as well.

Study objective

This study wants to evaluate on intraoperative MRI whether contrast enhancement at the borders of the resection cavity correlates with tumor tissue, and whether no contrast enhancement correlates with the absence of tumor tissue. To differentiate there will be particular attention for the shape and size of

contrast enhancement. This will be compared with a quantitative analysis of the biopsies (cellular density, proliferation and vascularisation).

Study design

Included patients will be operated by a neurosurgeon who has experience with the use of intraoperative MRI (H van Santbrink, dr M ter Laak-Poort of dr O Schijns). Before and after surgery a WHO Performance Scale will be scored. During surgery, separate biopsies will be taken from the border of the resection cavity. These biopsies are collected with the aid of navigation, to correlate the shape and size of the possible enhancement with the histological findings. The neuropathologist will not only present a histological diagnosis, but he will also provide a quantitative analysis regarding cell density, proliferation and vascularisation of the tissue. These results will be compared to the intraoperative MRI scan to answer the study question.

Intervention

Intraoperative MRI guided resection of a brain tumor with navigation guided biopsies from the borders of the resection cavity after acquiring intraoperative MRI images.

Study burden and risks

For patients there will be no additional burden by participating in this study, except that the surgery will take 90-120 minute longer. Of course brain surgery has its risks, but the risk profile is not likely to be increased by this study. The study protocol contains supportive literature references on this topic.

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 MRI suspect for a high grade glioma
- indication for resection of the tumor
- age >= 18 years
- WHO Performance Scale <= 2
- ASA class <= 3
- good knowledge of the Dutch language
- informed consent

Exclusion criteria

- recurrent tumor
- multiple tumor localizations
- prior radiotherapy on the skull
- prior chemotherapy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-10-2008
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	14-09-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-11-2008
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
CCMO	NL17679.068.07