Image guidance in neurosurgery: Flatpanel-Detector Parenchymal Blood Volume imaging and Magnetic Resonance - Dynamic Contrast Enhanced perfusion imaging in meningiomas

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

Summary

ID

NL-OMON49397

Source
ToetsingOnline

Brief title
Image guidance in neurosurgery: FD-PBV and MR-DCE in meningeomas

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system, skull and spine therapeutic procedures

Synonym
meningeal tumor, Meningioma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Siemens

Intervention

Keyword: FD-PBV, Image-guided neurosurgery, Meningiomas, MR-DCE

Outcome measures

Primary outcome

Primary objective of this study is to assess the feasibility of FD-PBV imaging in meningiomas; image quality of scans including reconstructed colour coded maps and vascular images will be evaluated by neurosurgeons and an experienced neuroradiologist using a standardized scoring form. Besides a descriptive analysis of this new application, yielded images and hemodynamic parameters will be compared with MR-DCE perfusion imaging and current literature.

Secondary outcome

Secondary endpoints of this study include:

- Added value in neurosurgery, assessed by a neuroradiologist and operating neurosurgeon,

- Practical workflow, extra time spent under general anaesthesia, effective contrast/radiation dose and learning curve,

- (Intraclass) correlation coefficients calculated of the obtained hemodynamic parameters between imaging techniques.

Study description

Background summary

The Hybrid - Operating Room (OR) at the Radboudumc is equipped with a robotic Flatpanel Detector - CT (FP-CT) which facilitates innovative image guided interventions. This FD-CT can provide peri-operative feedback on cerebral hemodynamics and is a potential valuable and easy technique for image guidance in neurosurgery and minimally invasive interventions. As FP-CT has been studied extensively in healthy subjects and stroke patients, this study will be an important step towards image guidance in the focal treatment and removal of brain tumors.

Study objective

The primary objective of this clinical pilot study is to explore the feasibility of Flatpanel Detector - Parenchymal Blood Volume (FD-PBV) imaging in patients with intracranial meningiomas during neurosurgery in the Hybrid-OR. Image quality, added value in neurosurgery and workflow/logistics will be evaluated. Image quality and hemodynamic parameters will be compared with Magnetic Resonance - Dynamic Contrast Enhanced (MR-DCE) perfusion imaging.

Study design

This is an explorative prospective clinical pilot study. MR-DCE perfusion imaging will be added to the standard pre-operative MRI used for neuro-navigation in neurosurgery. In seven patients, FD-PBV imaging will be performed at the day before surgery. These patients are awake. The last three patents will be scanned while under general anesthesia, with the skull fixated in a carbon head clamp to assess the influence of positioning of the head and the radiolucent carbon head clamp used during surgery.

Study burden and risks

The overall burden for patients in this study consists of an extension of the already performed MR scan, and one FD-PBV imaging acquisition at the day of surgery. The MR perfusion scan will be combined with the standard-of-care MR neuro-navigation performed 1 to 3 days before the surgery, effectively adding 5 minutes. FD-PBV acquisitions will be done at the Hybrid-OR. In 7 patients this will be done while they are awake, in 3 patients this will be done while under general anaesthesia, right after fixating the head in the head clamp. For these three patients, time spent under general anaesthesia will be prolonged ~15 minutes.

All contrast agents will be administered intravenously; contrast dose for the MRI will be increased from 15 ml to 27,5 ml of gadolinium chelate (Dotarem) and total contrast load for FD-PBV imaging is 80 ml of 300 mg/ml iodinated contrast (Iomeprol). Total effective radiation exposure of FD-PBV imaging will be 1.6-3.0 mSv (depending on positioning of the head and presence/absence of the carbon head clamp). Effective doses are confirmed by the manufacturer,

literature reports and in house dose measurements.

There are no direct benefits for patients participating in this study. As the feasibility of cerebral FD-PBV imaging has already been demonstrated in healthy patients and a variety of cerebrovascular diseases in the angiographic room, further research exploring intra-operative applications has to be performed in neurosurgical patients. Results of this study will be used to improve image guidance in neurosurgery and minimally invasive interventions including focal treatment of brain tumors and deep brain stimulation.

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

- Diagnosed with an intracranial meningioma, located above the tentorium in

convexity or falx.
- Scheduled for resection via craniotomy, including standard pre-operative MRI.
- Age >= 50 years

Exclusion criteria

- History of intracranial surgery
- History of major stroke with residual morbidity, significantly altering intracranial hemodynamics (e.g. large vessel occlusion)
- Impaired kidney function (eGFR < 45 ml/min/1.73m2)
- History of genetic disease increasing the risk of (radiation-induced) cerebral malignancies:
Multiple Endocrine Neoplasia (MEN), Neurofibromatosis (NF), von Hippel-Lindau disease (VHL)
- Allergy to iodine or gadolinium contrast agents
- MR-related contraindication: ferromagnetic implants, claustrophobia etc.

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):	23-06-2022
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	05-05-2021

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70461.091.20