Exploring the use of optical coherence tomography and hyperspectral imaging in glioma detection during surgery

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Primary Objective: To assess whether both OCT (optical coherence tomography) and/or HSI (hyperspectral imaging) detect differences in glioma tissue as compared to healthy tissue as examined during brain-surgery.Secondary Objective(s): To assess if...

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

Summary

ID

NL-OMON44150

Source
ToetsingOnline

Brief title
OCT and HSI in glioma surgery

Condition

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

Synonym
glioma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: glioma, HSI, OCT

Outcome measures

Primary outcome

Comparison of average spectrum of tumour tissue and healthy brain (cortical and subcortical) for HSI.

Comparison of image characteristics of tumour tissue and healthy brain (cortical and subcortical) for OCT.

Secondary outcome

In each dataset (HSI and OCT) clusters of characteristics will be examined that result in most efficient detection of tumour tissue.

Study description

Background summary

Surgery is a very important part of glioma treatment (followed with radiotherapy and chemotherapy). The best survival is seen when the tumor is resected as much as possible. Resection is hampered by difficulties in visualizing tumour and differentiating from normal tissue. The use of HSI/OCT seems promising especially for distinguishing LGG, since no other technique exists to achieve this. In high grade tumors fluorescent techniques have already shown to distinguish healthy brain from tumor tissue and improve (progression-free) survival. This technique has several draw-backs: it is costly (about ¤1000 per patient), involves ingestion of an agent (5-aminolevulinic acid) with possible side effects and does not visualize the infiltrative zone of the tumour very well.

The aim of this project is to develop an intra-operative, real-time visualization, that surgeons can use for accurate detection of glioma in order to extend survival and quality of life of the patient.

Study objective

Primary Objective:
To assess whether both OCT (optical coherence tomography) and/or HSI (hyperspectral imaging) detect differences in glioma tissue as compared to healthy tissue as examined during brain-surgery.

Secondary Objective(s):
To assess if either technique can discern a characteristic pattern that enables automatic detection of pathological tissue.
Can a combination of these techniques discern such a pattern?

Study design

Study design is that of a case control study in which healthy brain and in vivo glioma tissue will be imaged during brain tumour surgery. This design facilitates the best possible control group (same subject, same brain to compare glioma with), but also it represents the exact circumstances in which possible future application of the tested imaging techniques will be applied.
We aim at inclusion of 3 low grade and 3 high grade glioma patients and we want to collect 5 images of normal brain surface, 5 images of glioma surface, 5 images of subcortical glioma and (when available) 5 images of normal subcortical tissue in each subject. The spatial resolution of the HSI image depends on the optics; a large field of view will lower its resolution. In practice the resolution will be sub mm. Each OCT picture consists of vast amounts of data points. This will yield enough data for extensive comparison of imaging data.
Data collection takes place during surgery at the Radboud university medical center. Each year about 80 glioma patients are operated here, half of whom carry al low grade glioma. Since some patients will only be biopsied and glioma incidence varies, if we take into account that half of the available patients will or can participate, inclusion of 6 patients will most probably will take less than 3 months.

Study burden and risks

There are no anticipated additional risks for the participants since the OCT and HSI are non-invasive imaging methods based on the interaction of tissue and light, which is harmless to the patient. However, the operation time is prolonged with a few about 20 minutes.

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

glioma and planned surgery

Exclusion criteria

Histopathological diagnoses is not glioma

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-03-2016
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	Hyperspectral imaging and optical coherence tomography
Registration:	No

Ethics review

Approved WMO Date:	03-02-2016
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	NL53226.091.15