The ultrasound glioma study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28737

Source
NTR

Brief title
US-GLIOMA

Health condition

braintumor, glioma
hersentumor, glioom

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Stichting Coolsingel

Intervention

Outcome measures

Primary outcome

The extent of resection will presented as a dichotomous outcome: gross-total resection or sub-total resection.
Gross-total resection: No residual contrast enhancement on post-operative MRI scans (within 48 hours); 100% of all contrast enhancing tumor has been resected when compared to initial enhancing tumor on pre-operative MRI scans.
Sub-total resection: Residual contrast enhancement on post-operative MRI scans (within 48

hours); <100% of all contrast enhancing tumor has been resected when compared to initial enhancing tumor on pre-operative MRI scans.

Secondary outcome

The extent of resection (%) is a secondary outcome measurement defined as the residual tumor volumes on post-operative MRI studies compared to the operative tumor volume. Patients will be followed for 6 months and the neurological outcome (KPS), Quality of Life (EORTC QLQ-C30,QLQ-BN20), surgery associated neurological deficits (measured 1 month after date of surgery), adverse events and time of survival (days) will be assessed as a secondary outcome measurement.

Study description

Background summary

The main goal of high grade glioma (HGG) surgery is to achieve gross total resection (GTR) without causing new neurological deficits1-8. Intraoperative navigated high resolution ultrasound (US) is a promising new tool to acquire real-time intraoperative images to localize and to resect gliomas9-12. The purpose of this study is to investigate the effectivity of intraoperative navigated US in achieving GTR in patients with HGG, measure influence on quality of life and cost effectiveness.

Study objective

Ultrasound guided high grade glioma surgery succeeds gross total resection more frequently and improves quality of life and survival of time when compared with surgery without ultrasound guidance.

Study design

pre operative

post operative

1 month post- operative

3 month post- operative

6 month post- operative

12 month post- operative

Intervention

The study consists of two treatment arms: non-ultrasound guided glioma resection (conventional treatment) versus ultrasound guided glioma resection (intervention) .

Contacts

Public
Fatih Incekara
Rotterdam
The Netherlands
Scientific
Fatih Incekara
Rotterdam
The Netherlands

Eligibility criteria

Inclusion criteria

- Individuals between 18-75 years

- Newly diagnosed, untreated, contrast enhancing presumed high-grade glioma

- KPS ¡Ý 60

- Preoperative intention to perform gross-total resection of the enhancing tumor

- Written informed consent conform ICH-GCP

Exclusion criteria

- Tumours crossing the midline basal ganglia, cerebellum, or brain stem prohibiting gross total resection

- Multifocal contrast enhancing lesions

- Pre-existing neurological deficit (e.g. aphasia, hemiparesis) due to neurological diseases (e.g. stroke)

- Inability to give consent because of dysphasia or language barrier

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2016
Enrollment:	0
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-08-2016
Application type:	First submission

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
NTR-new	NL5853
NTR-old	NTR6033
Other	ABR-nummer//METC Erasmus MC : 49175//NL49175.078.15

Study results