Dose and Volume Escalation of Preoperative Brain Irradiation in GBM Patients
- the POBIG trial

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* To explore the single fraction dose and volume that can be safely given in a preoperative setting additional to the standard treatment of postoperative surgery and (chemo)radiation. * To assess the tumor control and (re)growth between surgery and...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON46343

Source
ToetsingOnline

Brief title
POBIG

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumour, Glioblastoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Antoni van Leeuwenhoek-RT research;KWF aanvraag in juni 2018

Intervention

Keyword: brain, glioblastoma, radiotherapy

Outcome measures

Primary outcome

* maximum tolerated dose (MTD)

* maximum tolerated irradiated volume (MTIV)

Secondary outcome

* Registration of postoperative surgical complications.

* Progression free survival.

* Overall survival.

Study description

Background summary

The prognosis of GBM patients is poor despite extensive therapeutic efforts with surgery, (chemo) radiation and adjuvant chemotherapy. Radiotherapy has shown to contribute significantly to the survival of GBM patients although doses above 60 Gy showed no further improvement. Gross total resection is a favorable prognostic factor for survival but microscopic total resection can never be achieved. Also, extensive surgery may lead to neurological deficits, which can deteriorate not only prognosis but also quality of life. In addition, wound factors released during and after surgery can provoke accelerated tumor cell proliferation and migration. In particular for GBM patients a relation between tumor regrowth between surgery and radiotherapy and prognosis has been shown. With our study of upfront radiotherapy we want to hit the tumor cells before surgery to reduce the proliferation and migration postoperatively. We hypothesize that this method will prevent or delay the regrowth of remnant tumor cells and will increase the effect of adjuvant (chemo)radiation in a safe

and feasible manner.

Study objective

* To explore the single fraction dose and volume that can be safely given in a preoperative setting additional to the standard treatment of postoperative surgery and (chemo)radiation.
* To assess the tumor control and (re)growth between surgery and post-operative radiotherapy.
* To confirm usability of the MRI to select GBM patients for preoperative single fraction radiotherapy
* To explore the effect of the tumor and therapy on the red and white blood cells
* To assess if there are any differences between the tumor characteristics of the irradiated part of tumor and the non-irradiated part of the tumor

Study design

Phase I/II study

Intervention

Single fraction preoperative radiotherapy.

Study burden and risks

Complications can occur during or as a result of the standard treatment. The preoperative radiation may cause the operation or the standard radiotherapy treatment to postpone due to edema complications after this radiation.
Other disadvantages
- the extra MRI scan and radiation will cost extra time
- Extra infusion for the MRI
- 2 tot 6 extra blood samples (5cc per sample)
- Starting dexamethasone if not already prescribed
- extra telephone consults

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

* 18 years or older
* Newly diagnosed GBM (based on MRI imaging or biopsy)
* Ability to undergo standard treatment consisting of (chemo)radiation and surgery (i.e. KPS > 70, indication that more than 70% of the tumor can be removed)
* Neuro-oncology multidisciplinary team consensus to include the patient for the current study
* Signed written informed consent

Exclusion criteria

* Prior or second invasive malignancy, except non-melanoma skin cancer, completely resected cervical or prostate cancer (with PSA of less than or equal to 0.1 ng/ml)
* Suspicion of primary tumor on CT thorax/abdomen in case no biopsy is available
* Inability to secure a *coldspot* in the tumor (volume of 2 cc of the contrast enhancing tumor that should not receive irradiation dose, see Chapter 2 and 4)
* Inability to secure radiotherapy dose constraints for organs at risk for either the neoadjuvant stereotactic radiosurgery or adjuvant fractionated radiotherapy (see Chapter 2 and 4)

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	04-06-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	12-07-2018
Application type:	Amendment
Review commission:	METC NedMec

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	NL63385.031.18