Imaging the response of glioblastoma brain tumours to treatment with radiotherapy and chemotherapy by magnetic resonance and positron emission tomography.

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

Summary

ID

NL-OMON31106

Source
ToetsingOnline

Brief title
Imaging the response of glioblastoma to treatment.

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain cancer, brain tumours

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Fluorothymidine Positron Emission Tomography (FLT-PET), Glioblastoma Multiforme, Magnetic Resonance Spectroscopy (MRS), Treatment respons

Outcome measures

Primary outcome

Patients will be followed during the standard treatment.

Before the neurosurgical operation, before and after the radiotherapy with concomitant chemotherapy, before the additive chemotherapy and after 2, 4 and 6 cycles of chemotherapy a MRI, MRS and FLT-PET scan will be made.

The operation, radiotherapy and chemotherapy will not be postponed for the scans. After the operation a MRI scan is made within 72 hours.

The response to therapy will be measured in progression free period, conventional radiological response and clinical response and be compared to the results of MRS and FLT-PET.

After the normal treatment the FLT-PET and MRS scans will continued together with normal follow up MRI scan depending on the results of the first 40 weeks.

Normally every 3 months.

The endpoint for the study is defined as the last patients last visit.

Secondary outcome

In the MR diagnostics protocol also diffusion- and perfusion weighted images are included. Changes in these images during the treatment will be correlated to the response of the tumour and compared to the results of the MRI, MRS and

PET.

Before the start of the additive chemotherapy the patients will be asked to

answer questions about the burden and convenience of the study.

Study description

Background summary

Gliomas are the most common primary brain tumours of which approximately 50% are high grade. The current treatment for malignant gliomas is neurosurgery to achieve maximal macroscopic debulking and additional treatment with radiotherapy and chemotherapy. Despite this aggressive treatment 74% of the patients with glioblastomas die within 24 months (Strupp, 2005).
Different new therapies are being developed. However, gliomas consist of different subgroups which respond different to radiotherapy and chemotherapy (Reardon, 2006). One major challenge is to image reliable and early the response of the tumours to treatment in a non-invasive way. With conventional Magnetic Resonance Imaging (MRI) this is not possible. Magnetic Resonance Spectroscopy (MRS) and Fluorothymidine Positron Emission Tomography (FLT-PET) are likely to be more convenient for this purpose. These techniques are not compared before.
With this study we want to compare different diagnostic techniques for measuring the response of glioblastoma to radiotherapy and chemotherapy.
This study is connected to the study of the biologic behaviour, molecular background and MR diagnostics of brain tumours in the UMC St Radboud.

Study objective

The main objective of the study is to compare the diagnostic power of Magnetic Resonance Spectroscopy, Fluorothymidine Positron Emission Tomography and conventional MRI in measuring the response of glioblastoma to radiotherapy and chemotherapy.
The secondary objective is combining MRS, FLT-PET, diffusion-weighted, perfusion-weighted and conventional MRI diagnostics for measuring the response of glioblastoma to radiotherapy and chemotherapy.

Study design

The study is an observational, longitudinal prospective pilot study.

Study burden and risks

There are no risks associated with participation in the study. Patients will visit the hospital maximal six times after the operation.
Every visit a MRI and MRS scan is performed which takes together approximately 45 minutes, a FLT-PET scan is performed which takes approximately 15 minutes after 1 hour waiting and a clinical examination of approximately 20 minutes is performed. The pre-operative and MRI-MRS scan made before start of the additional chemotherapy can replace the neuronavigation MRI and routinely follow-up MRI respectively. The PET-CT made before start of the radiotherapy can be used for planning of the radiotherapy.
There are no risks for the FLT-PET scan. With the exclusion criteria there is no risk for the MRI and MRS scan. There are no direct benefits for the patients. Patients will receive only a refund of travelling expenses.

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

Suspected intracranial glioblastoma on MRI eligible for operation
Contrast enhancement after gadolineum on T1-weighted MRI
Eligible for additional treatment with radiotherapy and chemotherapy after the operation
Informed consent
Adult, patients

Exclusion criteria

Karnovsky score < 70
Exclusioncriteria for MRI (eg known gadolinium allergy, pacemaker, neurostimulator, insulinepomp, defibrillator)
Patients with a post-operative proven non glioblastoma
Patients with a pre-operative non-enhancing FLT-PET scan
Pregnancy
Age > 70 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2007
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

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	NL17354.091.07