Phase II study of 18 F fluorothymidine Positron Emission Tomography (FLT-PET) in the follow up of glioblastoma multiforme (GBM) patients treated with combined radiotherapie and chemotherapy

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

Summary

ID

NL-OMON38320

Source
ToetsingOnline

Brief title
Using FLT-PET in the follow up of glioblastoma multiforme patients

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
braintumor, glioblastoma multiforme

Research involving

Human

Sponsors and support

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

Intervention

Keyword: biomarker, FLT-PET, follow up, glioblastoma multiforma

Outcome measures

Primary outcome

Comparison of FLT-PET treatment response defined as a more than 25% reduction in standardized uptake values (SUV) max at week 10 after start to MRI response at 22 and 34 weeks.

Secondary outcome

Correlation of FLT-PET response defined as a more than 25% reduction in standardized uptake values (SUV) max at week 10 after start radio/chemotherapy and OS at 6 months.

Study description

Background summary

First line treatment of patients with high grade brain tumours (glioblastoma multiforme GBM) consists of treatment with combined radiotherapy with chemotherapy (Temozolomide) after operation. This combination consists of 6 weeks of radiotherapy with daily oral intake of chemotherapy. After 4 weeks rest an MRI scan is conducted (MRI 10 weeks). Treatment will be continued with 6 courses of chemotherapy only and additional MRI*s are performed after 3 courses (MRI week 22) and 6 courses (MRI 34 weeks) of chemotherapy.
The evaluation of the first MRI scan (MRI 10 weeks) is complex; beside the tumour itself the scans show effects of surgery, radiation and chemotherapy. Progressive and enhancing lesions on this MRI scan, which are not only related to tumour progression, but which are a treatment effect is called

pseudoprogression. MRI*s performed at 22 and 34 weeks are less complex to evaluate and correlate better with treatment response. This study investigates if FLT-PET (FLT is an imaging biomarker for fast dividing cells) at 10 weeks proves superior to MRI at 10 weeks, to evaluate patients with newly diagnosed GBM treated with radio/chemotherapy. If FLT-PET proves superior this will lead for future patients to stop treatment with no clinical benifit, or start with a second line treatment.

Study objective

The aim of this study if PET using [18F] fluorothymidine (FLT), an imaging biomarker, performed at week 10 of concomitant radio/chemotherapy for patients with newly diagnosed GBM is superior to MRI at 10 weeks to evaluate treatment response and to predict if continuation of additional chemotherapy is useful.

Study design

To assess the ability of FLT-PET at 10 weeks to evaluate the response of combined radio/chemotherapy superior to MRI at 10 weeks in patients with newly diagnosed GBM, FLT-PET within 1 week before the initiation of treatment, and follow-up FLT-PET at 10 weeks after start of treatment and conventional MRI before, at 10 and at 22 weeks, will be performed.

Study burden and risks

This trial uses FLT-PET. Radioactivity of fluor has a short half life of 110 minutes. The total FLT radiation used in this trial is 6.2 mSv, this is half the amount of a normal CT scan.

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

• Patients with histologically confirmed newly diagnosed glioblastoma multiforme (World Health Organization [WHO] grade IV astrocytoma) with indication for radiotherapy and concomitant TMZ followed by adjuvant TMZ.
• Patients must have clinically and radiographically documented measurable disease. Conventional MRI post surgery must be performed within 28 days prior to start of combined treatment.
• Absence of inability to undergo MRI or PET scanning
• Patients >18 years of age
• WHO performance status of 2 or less
• Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial
• Before patient registration/randomization, written informed consent must be given according to ICH/GCP, and national/local regulations.

Exclusion criteria

Are formulated as 'no existence of' in inclusion criteria

Study design

Design

Study phase: 2

Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2009
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	13-03-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-10-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL26078.042.08