Phase II study of 18F fluorothymidine positron emmission tomography (FLTPET) in the follow up of glioblastoma multiforme patients treated with combined radiotherapy and chemotherapy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23615

Source
NTR

Brief title
FLTGBM

Health condition

Braintumor (GBM)

Sponsors and support

Primary sponsor: UMCGroningen
Source(s) of monetary or material Support: --

Intervention

Outcome measures

Primary outcome

Comparison of FLT-PET response defined as a more than 25% reduction in standardized uptake values (SUV) max (see section 7) at week 10 after start temozolomide/radiotherapy to MRI response at 22 weeks between pseudo progression and true progression.

Secondary outcome

1. Correlation of FLT-PET response defined as a more than 25% reduction in standardized uptake values (SUV) max (see section 7) at week 10 after start temozolomide/radiotherapy and OS at 6 and 12 months;

2. Correlation of Ki-67 proliferation index on tumor obtained by immunohistochemical staining with FLT ƒ¢SUV max uptake.

Study description

Background summary

The aim of this study is to assess the ability of PET using [18F] fluorothymidine (FLT), an imaging biomarker, performed at week 10 of treatment can discriminate between pseudo progression and true progression as measured by MRI at 10 and 22 weeks, in patients with newly diagnosed GBM treated with concomitant and adjuvant chemoradiotherapy with temozolomide.

Study objective

The aim of this study is to assess the ability of PET using [18F] fluorothymidine (FLT), an imaging biomarker, performed at week 10 of treatment can discriminate between pseudo progression and true progression as measured by MRI at 10 and 22 weeks, in patients with newly diagnosed GBM treated with concomitant and adjuvant chemoradiotherapy with temozolomide.

Study design

To assess the ability of FLT-PET to discriminate between pseudo progression and true progression as measured by MRI at 10 and 22 weeks in patients with newly diagnosed GBM treated with concomitant and adjuvant chemoradiotherapy with temozolomide baseline FLT-PET within 1 week before the initiation of treatment, and follow-up FLTPET at 10 weeks after start of treatment and conventional MRI before, at 10 and at 22

weeks, will be assessed. For secondary endpoints OS at 6 and 12 months, immunohistochemical staining for Ki-67 on tumor and MRI within 1 week before the initiation of treatment, and follow-up MRI at 10 and 22 weeks will be performed.

Intervention

To assess the ability of FLT-PET to discriminate between pseudo progression and true progression as measured by MRI at 10 and 22 weeks in patients with newly diagnosed GBM treated with concomitant and adjuvant chemoradiotherapy with temozolomide.

Baseline FLT-PET within 1 week before the initiation of treatment, and follow-up FLTPET at 10 weeks after start of treatment and conventional MRI before, at 10 and at 22 weeks, will be assessed. For secondary endpoints OS at 6 and 12 months, immunohistochemical staining for Ki-67 on tumor and MRI within 1 week before the initiation of treatment, and follow-up MRI at 10 and 22 weeks will be performed.

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Eligibility criteria

Inclusion criteria

1. Patients with histologically confirmed newly diagnosed glioblastoma multiforme (World Health Organization [WHO] grade IV astrocytoma) with indication and eligibility 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;

2. Absence of inability to undergo MRI or PET scanning;

3. Patients >18 years of age;

4. WHO performance status of 2 or less;

5. 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;

6. Before patient registration/randomization, written informed consent must be given according to ICH/GCP, and national/local regulations.

Exclusion criteria

1. Patients with no histologically confirmed newly diagnosed glioblastoma multiforme (World Health Organization [WHO] grade IV astrocytoma) or without indication and eligibility for radiotherapy and concomitant TMZ followed by adjuvant TMZ. No conventional MRI post surgery;

2. Inability to undergo MRI or PET scanning;

3. Patients <18 years of age;

4. WHO performance status of 3;

5. 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;

6. No written informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2009
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	26-10-2012
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	NL3518
NTR-old	NTR3680
Other	METC UMCG : 200.83.45
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A