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

Gepubliceerd: 26-10-2012 Laatst bijgewerkt: 18-08-2022

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,...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23615

Bron
NTR

Verkorte titel
FLTGBM

Aandoening

Braintumor (GBM)

Ondersteuning

Primaire sponsor: UMCGroningen
Overige ondersteuning: --

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Hanzeplein 1
A.M.E. Walenkamp
Groningen 9700 RB
The Netherlands
+31 (0)30 3616161

Wetenschappelijk

Hanzeplein 1
A.M.E. Walenkamp
Groningen 9700 RB
The Netherlands
+31 (0)30 3616161

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	02-12-2009
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-10-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3518
NTR-old	NTR3680
Ander register	METC UMCG : 200.83.45
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A