Observational study; Bevacizumab, Radiotherapy and Temozolomide Safety study in resected and irresectable primary GBM patients.

Gepubliceerd: 01-11-2007 Laatst bijgewerkt: 15-05-2024

Hypothesis in this trial is safe enhancement of the efficacy of chemoradiotherapy in resected and irresectable primary GBM patients, by using the anti-edema effect of bevacizumab and its vascular normalization response.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27467

Bron
Nationaal Trial Register

Verkorte titel
BERTES-01

Aandoening

1. Primary Glioblastoma Multiforme (NLD: primair Glioblastoma multiforme),;

2. bevacizumab;

3. temozolomide (NLD:radiotherapie).

Ondersteuning

Primaire sponsor: Departments of Neurosurgery, Radiation Oncology, Clinical Oncology and Neurology

Academisch Medisch Centrum
Meibergdreef 15
1105 AZ Amsterdam
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Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary objective is determination of safety of combination of standard treatment with 3 bevacizumab infusions, followed by the standard adjuvant cycles of temozolomide.

Toelichting onderzoek

Achtergrond van het onderzoek

Median survival for patients with a newly diagnosed GBM is 12.1 months after resection of the tumor to the maximum extent, followed by 60 Gy irradiation in 30 x 2 Gy fractions. Maximal surgical resection is not feasible in a sub-group of patients due to the localization of their tumor, resulting in poorer prognosis. In a selected group of patients the median survival was 14.6 months when resection was followed by radiotherapy in combination with temozolomide during and thereafter temozolomide 6 monthly cycles. Chemoradiotherapy with temozolomide is the current standard treatment for GBM in our center. New combination treatments are required to lengthen survival of GBM patients. This trial utilizes the anti-edema effect of bevacizumab and its vascular normalization response to enhance the efficacy of chemoradiotherapy in resected and irresectable primary GBM patients.

Doel van het onderzoek

Hypothesis in this trial is safe enhancement of the efficacy of chemoradiotherapy in resected and irresectable primary GBM patients, by using the anti-edema effect of bevacizumab and its vascular normalization response.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Study population will be treated with standard GBM chemoradiotherapy schedule plus

additional 3 infusions of the angiogenesis inhibitor bevacizumab at a dose of 10 mg/kg during irradiation (e.g. one dose every 2 weeks during 6 weeks radiotherapy).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with histologically proven GBM (biopsy or resection);

2. Can start 3-8 weeks post biopsy or surgery;

3. Mini-Mental Status Score >15;

4. Karnofsky >60;

5. Adequate bone marrow function;

6. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age <18 years;

2. Pregnancy;

3. Reluctance to use contraceptives;

4. Inability to comply with protocol or study procedures (for example, an inability to swallow tablets);

5. Bleeding disorders;

6. Anti-coagulant therapy;

7. Prior chemotherapy or radiotherapy.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2007
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 31960
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1113
NTR-old	NTR1148
CCMO	NL20411.018.07
ISRCTN	ISRCTN wordt niet aangevraagd/Observational study
OMON	NL-OMON31960

Resultaten

Samenvatting resultaten
N/A