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

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON27467

**Source**
NTR

**Brief title**
BERTES-01

**Health condition**

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

2. bevacizumab;

3. temozolomide (NLD:radiotherapie).

### Sponsors and support

**Primary sponsor:** Departments of Neurosurgery, Radiation Oncology, Clinical Oncology and Neurology
Academisch Medisch Centrum
Meibergdreef 15
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**Source(s) of monetary or material Support:** fund = initiator = sponsor

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

Secondary objectives: determination of:

1. efficacy;

2. classical response end-points;

3. tumor imaging biomarkers;

4. tissue samples biomarkers.

# Study description

### Background summary

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.

### Study objective

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.

### Study design

N/A

### Intervention

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).

## Contacts

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## Eligibility criteria

### Inclusion criteria

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.

### Exclusion criteria

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.

## Study design

### Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-12-2007 |
| Enrollment: | 20 |

Type: Actual

## Ethics review

Not applicable
Application type: Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 31960
Bron: ToetsingOnline
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

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

## Study results

**Summary results**
N/A