A RANDOMIZED PHASE III STUDY OF TEMOZOLOMIDE AND SHORT-COURSE RADIATION VERSUS SHORT-COURSE RADIATION ALONE IN THE TREATMENT OF NEWLY DIAGNOSED GLIOBLASTOMA MULTIFORME IN ELDERLY PATIENTS

Published: 24-02-2009
Last updated: 06-05-2024

To investigate if concomitant and adjuvant temozolomide chemotherapy improves survival in elderly patients that are managed with a short course of radiotherapy.

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

Summary

ID

NL-OMON39213

Source
ToetsingOnline

Brief title
temozolomide chemo-irradiation in elderly glioblastoma patients

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym

glioblastoma, grade IV brain tumor

Research involving
Human

Sponsors and support

Primary sponsor: European Organisation for Research in Treatment of Cancer (EORTC)
Source(s) of monetary or material Support: EORTC,Schering-Plough

Intervention

Keyword: elderly, glioblastoma, irradiation, temozolomide

Outcome measures

Primary outcome

overall survival

Secondary outcome

progression free survival, toxicity, quality of life

Study description

Background summary

Glioblastoma are the most frequent and the most aggressive primary brain tumors in adults. The standard of care for adults with glioblastoma consists of chemo-irradiation with temozolomide. It is unclear however if elderly patients (over 65 years of age) also benefit of this combined chemo-irradiation (as compared to treatment with radiotherapy only). In another study it has been shown that in elderly patients a shortened series of radiotherapy with a biologically equivalent dosage (40 Gy in 15 fractions) results in a similar outcome compared to 60 Gy in 30 fractions. This approach reduces the treatment time considerable. The question now is, whether the survival of elderly patients that are treated with a short course of radiotherapy is improved if this schedule is combined with temozolomide chemotherapy.

Study objective

To investigate if concomitant and adjuvant temozolomide chemotherapy improves survival in elderly patients that are managed with a short course of

radiotherapy.

Study design

prospective randomized phase III study

Intervention

daily 75 mg/m2 temozolomide (oral) concomitantly during the entire period of radiotherapy, followed by up to 12 cycles of adjuvant temozolomide at a dose level of 150-200 mg/m2 daily given day 1- 5 every 4 weeks.

Study burden and risks

The risks for the patients consist mainly of myelosuppresion, which if severe may cause severe leukopenia and thrombocytopenia. This may result in a bleeding tendency and a vulnerability for infections. Other side effects of temozolomide are usually mild and self limiting upon discontinuation. These more aspecific side effects (eg, like fatigue) can occasionally be pronounced. Apart from that is the participation to a study and all that comes with that potentially a burden for the patient. In view of the severity of the disease and its grave prognosis these risks appear however acceptable.

Contacts

Public
European Organisation for Research in Treatment of Cancer (EORTC)

av E Mounier 83/ bte11
1200 Brussel 9999
BE
Scientific
European Organisation for Research in Treatment of Cancer (EORTC)

av E Mounier 83/ bte11
1200 Brussel 9999
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Histopathologically confirmed newly diagnosed glioblastoma multiforme (GBM, WHO grade IV).
- The histological diagnosis must have been made after biopsy or neurosurgical tumour resection.
- Initial surgery/biopsy at diagnosis performed < 4 weeks (28 days) prior to randomization.
- Patient*s age is > 65 years.
- Patient is not deemed suitable by the treating physician to receive the standard radiotherapy regimen
- (60Gy/30 fractions over 6 weeks) in combination with temozolomide.
- ECOG performance status of 0, 1 or 2
- Patient may have received and continue to receive corticosteroids, but s/he have to be on a stable or decreasing dose for at least 14 days prior to randomization.
- Patient has not received prior chemotherapy or radiotherapy.
- Adequate hematological, renal and hepatic functions within 14 days prior to randomization
- Patients must be accessible for treatment and follow-up
- Informed consent

Exclusion criteria

- Patients with a history of other malignancies, except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer of the cervix, or other solid tumours curatively treated with no evidence of disease for > 5 years.
- Patients with a serious active infection (such as a wound infection requiring parenteral antibiotics) at the time of randomization or other serious underlying medical conditions that would impair the ability of the patient to receive protocol treatment.
- Patients with any condition (e.g. psychological, geographical, etc.) that does not permit compliance with the protocol.
- Patients with known hypersensitivity to temozolomide or compounds with similar chemical composition to temozolomide.
- Patients who have had treatment with any investigational cancer drug prior to randomization.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2009
Enrollment:	45
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	temodal
Generic name:	temozolomide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-02-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-05-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	11-11-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-01-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-07-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-09-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-09-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-06-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-07-2013

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-07-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-08-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2008-001949-26-NL
ClinicalTrials.gov	NCT00482677
CCMO	NL25615.078.09