Phase III intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with concomitant and adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma.

Published: 22-06-2010
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To determine the best treatment for anaplastich oligodendroglial tumors with combined 1p/19q loss, and to determine the optimal treatment with respect to the maintenance of a maximal neurological and cognitive functioning.

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

Summary

ID

NL-OMON44004

Source
ToetsingOnline

Brief title
Codeleted

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
anaplastic oligodendroglial tumors

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anaplastic oligoastrocytoma, anaplastic oligodendroglioma, combined 1p/19q loss, temozolomide

Outcome measures

Primary outcome

Overall survival, primary question: does the addition of temozolomide

chemotherapy to radiotherapy increase overall survival?

Secondary outcome

Time to event which is defined as the time from study registration to the

earliest evidence of 1) clinical progression, 2) radiographic progression, or

3) neurocognitive progression, whichever comes first

Study description

Background summary

The best treatment for anaplastic oligodendroglial tumors is present unclear. Previous studies have shown that these patients have a median survival of more than 7 years, and that these tumors respond favorably to both radiation therapy and chemotherapy. However, these studies failed to provide evident that chemotherapy given immediately after radiotherapy improves survival (although it was shown that adjuvant chemotherapy does improve progression free survival, but it remained unclear if that translates in a longer good clinical condition). Another study has observed an improved outcome in glioblastoma if radiotherapy is combined with temozolomide chemotherapy, it is however unclear if the addition of temozolomide to radiotherapy increases delayed neurotoxicities. Because of the prolonged survival of 1p/19q co-deleted

anaplastic oligodendroglioma these patients are longer at risk to develop radiotherapy associated delayed neurotoxicities. Because of these considerations, at present there is no agreement how these patients should be treated. The present study is designed to resolve this issue. Because of the potential of increased neurotoxicities if the initial treatment intensity is intensified, quality of life studies and evaluation of cognitive functioning are important secondary objectives.

Study objective

To determine the best treatment for anaplastich oligodendroglial tumors with combined 1p/19q loss, and to determine the optimal treatment with respect to the maintenance of a maximal neurological and cognitive functioning.

Study design

Three armed randomized phase III study.

Intervention

either 59.4 Gy radiotherapy in 33 fractions, the same radiotehrapy regimen in combination with concurrent and adjuvant temozolomide chemotherapy, or one year standard temozolomide chemotherapy

Study burden and risks

The treatments given within this study are standard of care for this patient population, and apart from the known risk and side effects do not impose further hazards. In addition to that, there are the known burdens of the participation to a study, like the filling in of quality of life questionnaires and the repeated neuropsychological evaluations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Provide informed written consent.
* Patient willing to provide tissue samples for deletion status
* *18 years of age.
* Newly diagnosed and <3 months from surgical diagnosis.
* Histological confirmation of anaplastic oligodendroglioma or mixed anaplastic oligoastrocytoma (grade 3-4)
* Loss of heterozygosity for both 1p and 19q (*co-deletion*).
* *2 weeks from the date of surgery and must have recovered from the effects of surgery
* Adequate hematological, renal and liver function
* Negative pregnancy test (B-HCG) done *7 days prior to registration, for women of childbearing potential only.
* Willing and able to complete neurocognitive/QOL questionnaire(s) by themselves or with assistance
* ECOG performance status (PS) of 0 1 or 2

Exclusion criteria

* For women: not pregnant or nursing, for all patients of childbearing potential: willing to employ adequate contraception
* No prior surgery, radiotherapy or chemotherapy for any CNS neoplasm
* No co-morbid systemic illnesses or other severe concurrent disease which, would interfere significantly with the proper assessment of safety and toxicity of the prescribed regimens.
* No concomitant serious immuno-compromised status (other than that related to concomitant steroids).

* No active uncontrolled systemic infection or HIV.
* Not receiving any other investigational agent which would be considered as a treatment for the primary neoplasm.
* No active other malignancy, excepting non-melanotic skin cancer or carcinoma-in-situ of the cervix. If there is a history of prior malignancy, they must not be receiving other specific treatment (other than hormonal therapy) for their cancer.
* No history of myocardial infarction *6 months, or congestive heart failure requiring use of ongoing maintenance therapy for life-threatening ventricular arrhythmias.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2011
Enrollment:	54
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	22-06-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-11-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-05-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-02-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-12-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-01-2017
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	EUCTR2008-007295-14-NL
ClinicalTrials.gov	NCT00887146
CCMO	NL31202.078.10