Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a Phase-II and observation study (EORTC 22042-26042)

Published: 20-08-2008
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This study investigate if, compared with the literature, an increased dosis of 70 Gy in 7 weeks will improve disease free survival against acceptable toxicity.

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

Summary

ID

NL-OMON32223

Source
ToetsingOnline

Brief title
EORTC Weber meningioma study

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
atypical and malignant meningioma

Research involving
Human

Sponsors and support

Primary sponsor: EORTC
Source(s) of monetary or material Support: EORTC

Intervention

Keyword: adjuvant radiotherapy, atypical meningioma, malignant meningioma

Outcome measures

Primary outcome

Disease free survival

Secondary outcome

Toxicity

Study description

Background summary

this question repeats many previous questions, particularly question c4 and protocol p. 7-9:

Meningiomas with atypical and malignant features have a high recurrence risk after neurosurgical resection, despite standard adjuvant radiotherapy (60 Gy).

Study objective

This study investigate if, compared with the literature, an increased dosis of 70 Gy in 7 weeks will improve disease free survival against acceptable toxicity.

Study design

This is a European multicenter phase II and obesrvational study of adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma (EORTC 22042-26042)

Intervention

High dose radiotherapy (70 Gy)

Study burden and risks

- Extended treatment time from 60 Gy in 6 weeks (10 min per work day) to 70 Gy in 7 weeks.
- Potentially more side effect; patients will during standard clinical and MRI follow-up be monitored for radiation-necrosis,
- During each standard out-patient visit, patient will receive the 11-item MMSE cognitive evaluation.

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

summary of protocol page 22:

Adult patients in a fair condition after resection of an intracranial atypical or malignant meningioma.

Exclusion criteria

not D4a

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL21893.018.08
Other	not relevant