Postoperative local stereotactic radiotherapy versus observation following complete resection of a single brain metastasis

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To improve local control following complete resection of a single brain metastasis using fractionated local stereotactic radiotherapy, whilst maintaining neurological functioning, neurocognition and quality of life.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON43850

Source
ToetsingOnline

Brief title
POLSOR study

Condition

- Metastases

Synonym
brain metastasis, tumor in the brain

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: brain metastasis, postoperative, radiotherapy, resection

Outcome measures

Primary outcome

The primary endpoint of this study is local control at the resection site at six months from the date of surgery, defined as the absence of nodular contrast-enhancing lesion(s) at the resection site on follow-up MRI scans, suspected for tumor recurrence and not radiation necrosis.

Secondary outcome

The secondary endpoints of this study are local control at 12 months, overall survival, and freedom from clinical-neurological progression. Other secondary endpoints are treatment-related toxicity, including radiation-induced necrosis, WHO performance score, steroid use, neurocognitive functioning and quality of life. The incidence of new lesions outside of the treated volume will be documented in both arms.

Study description

Background summary

A randomized EORTC trial published in 2011 showed equivalence in overall- and independent survival between groups treated with postoperative whole brain radiotherapy (WBRT) versus observation following complete resection of a single brain metastasis [Kocher 2011]. A subsequent analysis of health-related quality of life observed an inferior outcome after WBRT, although mostly transient [Sofietti 2013]. Local stereotactic radiotherapy of the surgical cavity can be a good alternative to both observation and to whole brain radiotherapy, However, this has not been investigated in a randomized way. The current study

aims to compare the outcome of local radiotherapy on the surgical cavity versus observation after complete resection in patients with a single brain metastasis of a solid tumor, in terms of local control, neurological functioning, neurocognition and quality of life.

Study objective

To improve local control following complete resection of a single brain metastasis using fractionated local stereotactic radiotherapy, whilst maintaining neurological functioning, neurocognition and quality of life.

Study design

Multicenter randomized phase III, with at least three high-volume Dutch centers participating in the trial. Stratification on primary tumor type and age.

Intervention

Patients will be randomized between observation alone (standard arm) and local stereotactic radiotherapy in three fractions of 8 Gy to the surgical cavity (study arm).

Study burden and risks

The burden for the patient associated with participation in the study is mainly due to three-montly filling in Quality of Life questionaires and a shortened neurocognitive testing at baseline, at 3, 6 and 12 months.

The risk of potential toxicity in the experimental (stereotactic radiotherapy) arm is estimated to be 5-10%, mainly in the form of fatigue and local hair loss. Occasionally, during radiation treatment-induced local swelling is observed, for which temporarily steroids have to be prescribed. Long-term side effects, i.e. radiation-induced necrosis, is anticipated to be observed in less than 5% of patients, of which symptomatic in half of these patients. If symptomatic, patients could be treated with steroids, or occasionally, surgery.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age of 18 years or older.
- Radiologically confirmed complete resection of a single brain metastasis on a contrast-enhanced MRI within 72 h after resection.
- Primary solid tumor, excluding hematologic malignancy, germ cell tumor, small cell lung cancer.
- Stable extracranial tumor (primary tumor and/or systemic metastases) during the last three months with or without treatment or progressive extracranial tumor and/or systemic metastases for which effective treatment is available.
- WHO performance score 0-2.
- Ability to provide written informed consent.

Exclusion criteria

- Prior treatment for brain metastases (i.e. surgery, stereotactic radiotherapy or WBRT).
- Distant brain metastases or radiological findings on MRI suspected for leptomeningeal tumor spread on the treatment planning MRI.
- Concurrent use of systemic therapy during local stereotactic radiotherapy

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):	21-09-2015
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	15-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2016
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2017
Application type:	Amendment
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	NL51283.029.14