The effect of stereotactic radiotherapy on cognitive functioning and quality of life of patients with one to three brain metastases: a prospective study

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To determine the effect of SRT on cognition and on quality of life of patients with one to 3 brain metastases, and to relate these outcome measures with radiological changes detected on MR imaging.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Observational non invasive

Summary

ID

NL-OMON32515

Source
ToetsingOnline

Brief title
Cognition and quality of life after SRT for brain metastases

Condition

- Metastases
- Nervous system neoplasms malignant and unspecified NEC

Synonym
Brain metastases; secondary brain tumours

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Medisch centrum Haaglanden

Intervention

Keyword: Brain metastases, Cognition, Quality of life, Stereotactic radiotherapy

Outcome measures

Primary outcome

Indicators of cognitive functioning, fatigue, quality of life and radiological features will be assessed as primary outcomes at baseline (before SRT), one month after completion of SRT, and again three months and six months after completion of SRT.

Secondary outcome

Neurological functioning and self care (in daily life)

Study description

Background summary

Currently, stereotactic radiotherapy (SRT) is one of the most used treatments for brain metastases. In comparison to WBRT and neurosurgery, the application of SRT is often less intensive and SRT is thought to be less harmful for healthy brain tissue. Therefore, fewer side effects would occur and also the effects on cognition, fatigue and quality of life should be less devastating than after WBRT. However, it is not yet known to what extent SRT might influence cognitive functioning and quality of life in patients treated with SRT for brain metastases. In addition, it is not known how possible radiological changes (e.g. tumour recurrence or the occurrence of radionecrosis) relate to cognitive and quality of life outcomes in these patients.

Study objective

To determine the effect of SRT on cognition and on quality of life of patients

with one to 3 brain metastases, and to relate these outcome measures with radiological changes detected on MR imaging.

Study design

A prospective trial will be undertaken to monitor cognitive performance, experienced quality of life and amount of fatigue, radiological features and functional status at different points in time, in patients with one to three newly diagnosed brain metastases who will be treated with SRT.

Study burden and risks

Only patients with brain metastases can participate in this study because of the research question. For the participating patients, the burden associated with participation consists of (1) completing a neuropsychological test battery and (2) completing questionnaires regarding fatigue and quality of life, at different visits to the hospital and at different points in time during the follow up period. Possible benefits of participation for the patients consists of (1) more frequent and better monitoring of possible cognitive dysfunction, complaints of fatigue, impaired quality of life and radiological outcomes, which could result in earlier and more individualised psychosocial education, other interventions or referrals to other medical disciplines.

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

1. Patient with * 3 newly diagnosed brain metastases,
2. Adult (* 18 years),
3. Patient will be treated with SRT,
4. Written informed consent.

Exclusion criteria

1. Patient has had any treatment (i.e. surgery, biopsy, WBRT and/or SRT) for his brain metastatic disease,
2. Patient will be treated with both WBRT and a SRT boost,
3. Patient has insufficient mastery of the Dutch language,
4. patient has other neurological or psychiatric conditions which could interfere with the results,
5. according to the treating physician, patient is (expected to be) unable to participate in the follow up period, because of serious physical or mental conditions (i.e. a KPS score below 70),

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	02-12-2008
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL25305.098.08