Cognitive Outcome after Gamma Knife Radiosurgery in Patients with Brain Metastases

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON28059

Source
Nationaal Trial Register

Brief title
The CAR study

Health condition

Brain metastases

Sponsors and support

Primary sponsor: St Elisabeth Hospital, Tilburg and Tilburg University
Source(s) of monetary or material Support: ZonMw (The Dutch Organisation for Health Research and Development)

Intervention

Outcome measures

Primary outcome

Cognitive functioning will be examined with a battery of neuropsychological tests: The revised Hopkins Verbal Learning Test (HVLT-R), WAIS Digit Span and Digit Symbol, TMT A and

B, COWA, and Grooved Pegboard.

Secondary outcome

1) Fatigue (MFI)

2) Health related QOL (FACT-BR)

3) Depression and anxiety (HADS)

4) Overall Survival

5) Local and distant tumor control

Study description

Background summary

Effective treatment for patients with brain metastases (BM) without negative cognitive side effects is increasingly becoming more important, since more patients survive and live longer after treatment. The proposed study is a single-arm, prospective study designed to evaluate changes over time in cognitive function in adult patients with BM scheduled for treatment with GKRS in the Netherlands. Neuropsychological assessment will be performed at baseline (before GKRS). Follow-up at 3, 6, 9, 12, 15, and 21 months (cognitive testing) and 3-monthly MRI scan. Ultimately, the purpose of this line of research is to inform individual patients with BM more precisely about the (long-term) cognitive effects and the consequences they can expect from treatment with GKRS. This will enable patients and doctors to make a better-informed treatment decision grounded on scientific evidence.

Study objective

The main objective is to assess cognitive functioning over time in patients with multiple (1-10) brain metastases (BM) after Gamma Knife Radiosurgery (GKRS). Improvements and/or declines in memory, executive function, attention, processing speed, and upper extremity fine motor dexterity will be determined at baseline (before GKRS treatment) and subsequent follow-ups.

Study design

The neuropsychological test battery, including questionnaires, will be administered at baseline (before GKRS) and 3, 6, 9, 12, 15 and 21 months after treatment.

Intervention

Patients will complete a standardized battery of neuropsychological test both at baseline and 3, 6, 9, 12, 15, and 21 months post GKRS.

Contacts

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Eligibility criteria

Inclusion criteria

28-okt-2016:
• Histologically proven malignant cancer

• Imaging and clinical presentation consistent with BM; contrast enhanced volumetric MRI used for treatment planning showing 1-10 newly diagnosed BM with a maximum total tumor volume of 30 cm3

• Lesion >3mm from brainstem or optic apparatus

• Patient age >/=18 years

• Karnofsky Performance Status ≥70

• WHO performance status ≤2

• Anticipated survival (independent of the BM) greater than 3 months

• Patient informed consent obtained (verifying that patients are aware of the investigational nature of this study).

Exclusion criteria

28-okt-2016:
• No prior histologic confirmation of malignancy

• Primary brain tumor, a second (active) primary tumor

• Lymphoma

• Small cell lung cancer

• Leukemia

• Meningeal disease

• Progressive, symptomatic systemic disease without further treatment options

• Prior brain radiation

• Prior surgical resection of BM

• Additional history of a significant neurological or psychiatric disorder

• Participation in a concurrent study in which neuropsychological testing and/or health-related QOL assessments are involved

• Contra indications to MRI or gadolinium contrast

• Underlying medical condition precluding adequate follow-up

• Lack of informed consent

• Patients unable to complete test battery and/or study questionnaires due to any of the following reasons; lack of basic proficiency in Dutch, IQ below 85, severe aphasia and paralysis grade 0-3 according to MRC scale (Medical Research Council

Study design

Design

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2015
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-09-2015
Application type:	First submission

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
NTR-new	NL5352
NTR-old	NTR5462
Other	Project number ZonMw; Protocol ID MEC : 842003008; P1515

Study results