Cognitive outcome after Gamma Knife Radiosurgery in patients with brain metastases

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Primary Objective Our primary aim is to evaluate the course of cognitive functioning (stability, impairment or decline, or improvement as compared to Dutch controls) after usual care SRS in patients with 1-10 BM at time of treatment initiation....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43670

Source
ToetsingOnline

Brief title
Cognitive outcome after GKRS

Condition

- Other condition
- Metastases
- Nervous system neoplasms malignant and unspecified NEC

Synonym
Brain metastases, brain tumor

Health condition

cognitieve stoornissen

Research involving

Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Brain Metastases, Cognitive Function, Gamma Knife, Stereotactic Radiosurgery

Outcome measures

Primary outcome

* Cognitive functioning as assessed 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

* Fatigue (MFI)

* Health related QOL (FACT-BR)

* Depression and anxiety (HADS)

* Overall Survival

* Local and distant tumor control

Study description

Background summary

Stereotactic radiosurgery (SRS) is at the least an equally effective treatment for brain metastases (BM) with regard to survival and tumor control as is whole brain radiation therapy (WBRT). SRS is expected to cause fewer cognitive side effects. However, cognitive effects of SRS have not been examined with formal neuropsychological testing, except for the studies by Chang et al (2007; pilot n=15, 2009; n=30 in the SRS arm), which are considered landmark studies despite their small sample sizes. Our aim is to assess cognitive functioning over time

in patients with BM after treatment with SRS in a sufficiently large sample.

Study objective

Primary Objective
Our primary aim is to evaluate the course of cognitive functioning (stability, impairment or decline, or improvement as compared to Dutch controls) after usual care SRS in patients with 1-10 BM at time of treatment initiation. Improvements and/or declines in memory, executive function, attention, processing speed, and upper extremity fine motor dexterity will be determined at baseline (before SRS treatment) and 3, 6, 12, 9, 15 and 21 months after treatment.

Secondary Objectives
* To determine overall survival
* To determine local and distant tumor control in the brain at 3, 6, 9, 12,15 and 21 months post treatment
* To assess psychological functioning (fatigue, depression and anxiety) and health related Quality of Life (QOL) both at baseline and 3, 6, 9, 12, 15, and 21 months post treatment
* To identify possible predictors of cognitive functioning (age, sex, number and cumulative volume of BM, extracranial disease status, type and duration of systemic and salvage therapies, local and distant control, psychological functioning) after treatment

Study design

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 SRS. Neuropsychological assessment will be performed at baseline (before SRS). Follow-up at 3, 6, 9, 12, 15, and 21 months (cognitive testing) and 3-monthly MRI scan.

SRS will be performed with a Leksell Gamma Knife® Icon, Electa Instruments, AB (Gamma Knife Radiosurgery: GKRS). Depending upon the volume of the BM, a dose of 18-25 Gy will be prescribed with 99-100% coverage of the target.

Study burden and risks

Neuropsychological assessments (existing of six tests and three questionnaires) will take mental effort. To reduce this effort as much as possible, a shortened neuropsychological test battery was chosen (90 minutes). Moreover, assessments will be combined with patients' hospital visits.
Ultimately, the purpose of this line of research is to assist both doctors and patients in individual decision-making with regard to the cognitive effects of

treatment with either WBRT or SRS.

Contacts

Public
Sint Elisabeth Ziekenhuis

Hilvarenbeekse Weg 60
Tilburg 5022 GC
NL
Scientific
Sint Elisabeth Ziekenhuis

Hilvarenbeekse Weg 60
Tilburg 5022 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Contrast enhanced volumetric MRI showing 1-10 newly diagnosed BM with a total tumor volume * 30cc
* Lesion > 3 mm from optic apparatus*
* Patient age * 18 years*
* Karnofsky Performance Status * 70, WHO performance status * 2*
* Anticipated survival (independent of the BM) greater than 3 months
Dutch healthy control subjects will be:
* Sociodemographically similar to the patient group
* In good health, with no current or past psychiatric, neurologic, or cognitive disorder, and

mediation-use that interferes with cognitive function

Exclusion criteria

* No prior histologic confirmation of malignancy
* Primary brain tumor, small cell lung cancer, lymphoma, leukemia, or meningeal disease
* Progressive, symptomatic systemic disease without further treatment options
* Prior brain radiation or 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
* 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, or paralysis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2015

Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-03-2017
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL53472.028.15

Study results

Date completed:	07-10-2019
Results posted:	25-11-2019
Actual enrolment:	101

First publication
08-10-2019