

Cognitive Outcome after Gamma Knife Radiosurgery in Patients with Brain Metastases

Gepubliceerd: 10-09-2015 Laatste bijgewerkt: 18-08-2022

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,...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON28059

Bron

Nationaal Trial Register

Verkorte titel

The CAR study

Aandoening

Brain metastases

Ondersteuning

Primaire sponsor: St Elisabeth Hospital, Tilburg and Tilburg University

Overige ondersteuning: ZonMw (The Dutch Organisation for Health Research and Development)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-10-2015
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	10-09-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten