

Pilot study investigating the relationship between neurocognitive function, radiotherapy and cerebral white matter microstructure in low grade glioma patients by using MRI diffusion tensor imaging

Published: 07-11-2018

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To determine the correlation between neurocognitive function and the incidence of DTI abnormalities on MRI in irradiated glioma patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON46061

Source

ToetsingOnline

Brief title

MRI DTI following radiotherapy for low grade glioma

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym

brain tumor, Low grade glioma

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Er al een subsidie-aanvraag bij het UMCG kanker research fonds gedaan worden

Intervention

Keyword: DTI / diffusion tensor imaging, Low grade glioma, Radiotherapy, White matter

Outcome measures

Primary outcome

The primary endpoint is the correlation between neurocognitive function and DTI abnormalities seen on MRI, expressed in fractional anisotropy (FA). Both will be analyzed as a continuous variable. DTI parameters and cognition will also be related to other MRI parameters.

Secondary outcome

n.a.

Study description

Background summary

Low grade gliomas occur in relatively young patients (between the ages of 30-50 years), have a good performance score, neurological function and neurocognitive function when diagnosed. Patients with grade II or III glioma and favorable prognostic features have a 10 year survival rate exceeding 50%. Standard treatment consists of surgical debulking followed by postoperative radiotherapy and chemotherapy.

Most patients develop cognitive dysfunction, which may greatly impact quality of life for the patient but also for the next of kin. It is reasonable to assume that cranial irradiation has a negative impact on neurocognitive functioning. This may become apparent only after 5-10 years.

Diffusion tensor imaging (DTI) is an MRI-technique that can provide insight into the microstructural integrity of cerebral white matter. It is more

sensitive to the detection of subtle white matter changes than conventional T1- and T2 weighted imaging. Several studies exist in which MRI DTI was used to study the effects of radiotherapy on white matter. These indicate the existence of a dose-effect relationship as well as the existence of a relationship between neurocognitive dysfunction and microstructural damage as revealed by MRI DTI. However, these studies had very limited patient numbers and report conflicting results.

Study objective

To determine the correlation between neurocognitive function and the incidence of DTI abnormalities on MRI in irradiated glioma patients.

Study design

All patients that are in follow up receive an MRI-scan bi-annually. This scan will be extended by 15 minutes to allow running the abovementioned DTI sequence. Scans will be obtained on the 3 Tesla (Prisma) scanner. Measuring neurocognitive function in patients is standard care and will be performed by the treating neurologist or another health care provider. Afterwards, the correlation between neurocognitive function and DTI abnormalities will be investigated. Anatomical changes will be related to the irradiated volume.

Study burden and risks

Patients do not benefit from participation in this study. Standard diagnostic and therapeutic procedures remain unchanged, regardless of any study outcomes. Participants will not incur any additional costs if they participate. There will be no financial reimbursement. The extra burden for participating patients is elongation of their next MRI examination by 15 minutes (55 instead of 40).

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

- WHO grade II or III glioma
- Radiotherapy received and still in follow-up, both in the UMCG

Exclusion criteria

- Younger than 18 years at the time of glioma diagnosis
- Disease progression requiring additional treatment since radiotherapy
- MRI contra-indicated

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 03-01-2019
Enrollment: 45
Type: Actual

Ethics review

Approved WMO
Date: 07-11-2018
Application type: First submission
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO
Date: 11-12-2018
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL67337.042.18