Pilot to validate in vivo 2-HG MR spectroscopy in low grade gliomas

Published: 21-03-2018
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Primary goal is to investigate if the 2-HG peak on in vivo MR spectroscopy correlates with the ex vivo IDH mutation and 2-HG concentration in patients with a low grade gliomas.

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

Summary

ID

NL-OMON46642

Source
ToetsingOnline

Brief title
Validation of 2-HG MRS

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
Low grade glioma; brain tumour

Research involving
Human

Sponsors and support

Primary sponsor: afdeling Radiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 2-HG, IDH, Low grade glioma, MRS

Outcome measures

Primary outcome

Primary endpoint is firstly the correlation between the presence of the IDH mutation and the presence of the 2-HG peak on MR spectroscopy (binary variables). Also primary endpoint is the correlation between the concentration of 2-HG on in vivo MR spectroscopy and ex vivo in the tissue in mmol/mg (continue variables).

Secondary outcome

Not applicable.

Study description

Background summary

Low grade gliomas are brain tumors that occurs mainly in young adults. The mean survival is about 10 years. The tumor might be difficult to resect if located near an important brain area. Treatment is best done using radiotherapy and chemotherapy in such cases. However, the diagnosis should be established with certainty with a brain biopsy. However, a biopsy induces the risk of brain damage. Unfortunately, a brain biopsy is the only way to establish the diagnosis with certainty currently.
An alternative seems possible. Low grade gliomas have a IDH gene mutation. This mutation results in the production of 2-hydroxyglutarate (2-HG). 2-HG seems to be measurable on a specific MRI sequence, MR spectroscopy.
The current pilot study will investigate if this IDH gene mutation indeed result in the presence of 2-HG on MRI. We also validate if the concentration measured on MRI correlate with the concentration measured in the tissue.
If indeed positive, we are able to set-up an follow-up study (not part of the current protocol) to see if the 2-HG MR scan could replace a brain biopsy in patient with a low grade gliomas.

Study objective

Primary goal is to investigate if the 2-HG peak on in vivo MR spectroscopy correlates with the ex vivo IDH mutation and 2-HG concentration in patients

with a low grade gliomas.

Study design

A pilot study to validate 2-HG spectroscopy in patients with a low grade glioma.

Study burden and risks

Participants will not have and advantages from participation in the research. The standard clinical diagnostic and therapeutic procedures will not change. Participants will have no additional costs and will not receive any financial compensation. The discomfort is that they will have to lay down 15 minutes longer in the already planned MRI scan. The MRI will last 55 minutes instead of 40 minutes.

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

Patients with a low grade glioma >= 18 years old that are planned to undergo surgery and have given written informed consent

Exclusion criteria

- Patients with recent cerebral radiotherapy or surgery (<3 months)
- Age < 18 years
- General contra-indications for MRI which are non-MRI compatible ferromagnetic material, pregnancy (or possible pregnancy) and claustrophobia.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-05-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	21-03-2018
Application type:	First submission

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

ID: 24067
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64707.042.18
Other	NTR volgt
OMON	NL-OMON24067