

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

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24067

Source

NTR

Health condition

2-HG
MRI
Spectroscopy
Low grade glioma
IDH

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Universitair Medisch Centrum Groningen

Intervention

Outcome measures

Primary outcome

Primary endpoint is the correlation between the presence of the IDH mutation and a 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, uitgedrukt in mmol/mg (continue variabelen).

Secondary outcome

not applicable

Study description

Background summary

Background of the study: 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.

Objective of the study: 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 population: Patients with a low grade glioma ≥ 18 years old that a planned to undergo surgery (N=10).

Primary study parameters/outcome of the study: 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).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable): 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.

Study objective

We expect that patients with a IDH mutation demonstrate an increase in 2-HG on MR spectroscopy. We also expect a positive correlation between in vivo 2-HG on MR spectroscopy and ex vivo concentration in tissue.

Study design

pre-operative MR Spectroscopy. 2-HG tissue concentration measurement post-operative ex-vivo.

Intervention

MR spectroscopy for 2-HG.

Contacts

Public

Department of radiology (EB44), University Medical Center Groningen

A. Hoorn, van der
PO Box 30 001

Groningen 9700 RB
The Netherlands
+31503616161

Scientific

Department of radiology (EB44), University Medical Center Groningen

A. Hoorn, van der
PO Box 30 001

Groningen 9700 RB
The Netherlands
+31503616161

Eligibility criteria

Inclusion criteria

Patients with a low grade glioma ≥ 18 years that are planned to undergo surgery

Exclusion criteria

- Patients with recent cerebral radiotherapy or operation (<3 months).
- Age <18 years.
- General contra-indications for MRI (non compatible material , pregnancy or claustrophobia)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-03-2018
Enrollment:	10
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:

Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46642

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6798
NTR-old	NTR6984
CCMO	NL64707.042.18
OMON	NL-OMON46642

Study results