2-HG spectroscopy in low grade glioma patients treated with vorasidenib - a pilot study

Published: 25-07-2024
Last updated: 21-12-2024

Primary objective is to study the association with preoperative 2-HG concentration, and progression free time in patients with a low grade glioma that are treated with vorasidenib.

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

Summary

ID

NL-OMON56925

Source
ToetsingOnline

Brief title
2-HG MRS and vorasidenib

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
low grade brain tumor, Low grade glioma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 2-HG, Low grade glioma, MR spectroscopy, Vorasidenib

Outcome measures

Primary outcome

Primary outcome is the association between preoperative 2-HG levels (measured with MR spectroscopy) an progression free time in patients with low grade gliomas that are treated with Vorasidenib. Progression is defined according to the RANO LGG criteria.

Secondary outcome

NA

Study description

Background summary

Lowgrade gliomas are brain tumors that are found in adolescents and young adults. Up to now the only treatment was surgery with concomittand chemoradiation or primary chemorafiation. All lowgrade gliomas have a IDH genmutation, which leads to the production of 2-hydroxyglutararate (2-HG). 2-HG can be measured with a specific MRI, MR spectroscopy. 2-HG is associated woth disease progression and survival. Recently a study was published in which patients that are treated with an inhibitor of 2-HG (vorasidenib) show longer progression free time. Our hypothesis is that patients with higher 2-HG concentrations will have better response to vorasidenib treatment, with longer progression free time. In future studies these findings might aid in selecting patients that will benefit from vorasidenib therapy.

Study objective

Primary objective is to study the association with preoperative 2-HG concentration, and progression free time in patients with a low grade glioma that are treated with vorasidenib.

Study design

Pilot study assessing the relationship between preoperative 2-HG levels and progression free time in patients with lowgrade gliomas that are treated with vorasidenib

Study burden and risks

Participating patients do not benefit grom this study. They will receive normal diagnostic and therapeutic procedurs. There are no extra costs for participants, and they do not receive compensation.The only discomfort is a one time longer MRI time of 15 minutes.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Low grade glioma patients (WHO II), either suspected or histologically proven.
treated with vorasidenib
Signed informed consent.

Exclusion criteria

Age <18 years old.
Contra-indication for MRI.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2024
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	25-07-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL86417.042.24