Pilot study for the treatment response evaluation in glioblastoma with vessel architectural imaging (VAI)

Published: 31-10-2018
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To determine the diagnostic accuracy of VAI for the differentiation of treatment effects from tumour progression.

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-OMON46808

Source
ToetsingOnline

Brief title
VAI pilot study in glioblastomas

Condition

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

Synonym
brain cancer, Brain tumour, GBM, glioblastoma multiforme

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Van der Meer Boerema stichting (B.R.J. van Dijken). Deze beurs geldt als aanvulling op de MD/PhD beurs

van het UMCG aan BRJ van Dijken. Er gelden geen voorwaarden aan de ontvangen beurs.

Intervention

Keyword: Glioblastoma, MRI, Perfusion, Vessel Architectural Imaging

Outcome measures

Primary outcome

Primary endpoints are true positive, false positive, true negative, and false

negative values of VAI MRI. The reference will be definitive diagnosis

according to standard radiological follow-up.

Secondary outcome

Not applicable.

Study description

Background summary

The current conventional MRI techniques are not capable of reliably evaluating treatment response in glioblastomas. Progression of the tumour can not always be distinguished from treatment effects. More advanced MRI techniques that focus on the biological properties of the tumour are promising. Recently, a novel perfusion-MRI technique became available, vessel architectural imaging (VAI). VAI can visualise tumor neovascularisation. Glioblastomas demonstrate increased neovascularisation with subsequent hyperperfusion. This angiogenesis is seen as a key in the development of tumour progression. With VAI it is potentially possible to more reliably differentiate between tumour progression and treatment effects. The diagnostic accuracy of VAI for the treatment response evaluation in glioblastoma has never been investigated.

Study objective

To determine the diagnostic accuracy of VAI for the differentiation of treatment effects from tumour progression.

Study design

A prospective pilot study for the diagnostic accuracy of VAI for the treatment

response evaluation of patients with a glioblastoma.

Study burden and risks

Participants will not have any advantages from participation in the research. Participants will undergo one extra MRI scan (VAI) along their normal follow-up MRI schedule. This research scan is comparable with the standard clinical MRI scans. After intravenous administration of a contrast agent (gadolinium) scan time will be approximately 30 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

- Histological confirmed glioblastoma after standard treatment
- New contrast enhancing lesion on follow-up MRI
- Written informed consent

Exclusion criteria

- Minors (<18 years)
- Subtotal resection of the tumour resulting in residual enhancement on post-operative MRI
- History of previous new enhancing lesion on follow-up MRI
- Treatment different than standard treatment
- Contraindication for MRI (ferromagnetic material in body, pregnancy, claustrophobia)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	31-10-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	27-03-2023

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-07-2023
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	NL65208.042.18