Physiological MRI for precision radiotherapy of IDH-wildtype glioblastoma

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Generate proof-of-concept of using a physiological CTV for radiotherapy treatment planning for patients with brain tumours.

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

Summary

ID

NL-OMON51604

Source
ToetsingOnline

Brief title
PhysMRRT

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, glioblastoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Erasmus MC Trustfonds

Intervention

Keyword: IDH-wildtype glioblastoma, MRI, precision radiotherapy

Outcome measures

Primary outcome

Equal prediction of pattern of failure (locations of tumour recurrence) based

on the physiological CTV compared to the standard CTV used for radiotherapy

planning, with the physiological CTV being smaller in volume.

Secondary outcome

NA

Study description

Background summary

Current treatment management of patients with IDH-wildtype glioblastoma is sub-optimal because of two main issues: (1) Creating an accurate target volume for radiotherapy, a key aspect of glioblastoma treatment, containing all remaining tumour cells after surgery that is impossible with the conventional CT and MRI imaging techniques currently used and (2) in the follow-up of patients after radiotherapy, conventional MRI is incapable of distinguishing tumour progression from treatment effects. The solution to these issues lies in accurate and non-invasive assessment of physiological processes of tumour cells to enable delineation of the true physiological clinical target volume (CTV) for radiotherapy planning and to allow for early detection of true tumour progression during treatment follow-up.

Study objective

Generate proof-of-concept of using a physiological CTV for radiotherapy treatment planning for patients with brain tumours.

Study design

By extending the clinical standard MRI session used for radiotherapy planning in patients diagnosed with glioblastoma with advanced MRI techniques that assess oxygenation status and cell proliferation, a physiological CTV will be

generated for each patient in addition to the standard CTV. Treatment for each patient will be according to the current standard in which the standard CTV is used. Initial analysis will include comparing both CTVs in terms of volume and location. Patient follow-up will occur according to the clinical standard, including the standard MRI scan protocols, for a maximum of 2 years. Pattern-of-failure analysis will be done to compare the standard CTV and physiological CTV. It is hypothesized that the physiological CTV will be smaller than the standard CTV, whilst having the same pattern-of-failure.

Study burden and risks

The patients the burden of prolonged scan time (+ 30 minutes, scan will last 60 mins in total) during their standard RT planning scan. The remainder of their clinical care will not be altered: RT will be given to these patients based on standard CTVs. Follow-up will follow the clinical protocol . There will be no personal benefit for the patients in this research project.

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

• Informed consent;
• Adults (18 years or older);
• diagnosed with IDH-wildtype GBM, as confirmed by pathology including molecular analysis post resection/biopsy;
• referred to outpatient clinic of the Department of Radiotherapy to undergo standard treatment with high-dose RT.
• Patients eligible for 30x2Gy or 15x2.67Gy

Exclusion criteria

• Contraindication for MRI
• Contraindication for use of gadolinium-based contrast agent (i.e. subject having renal deficiency)
• Unable to give informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2022
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Date:	14-07-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL80747.078.22