Glucose metabolism in brain tumours: comparing glucoCEST MRI with [18F]FDG-PET

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Ethical review	Approved WMO
Status	Pending
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON51824

Source
ToetsingOnline

Brief title
GlucoCEST MRI vs [18F]FDG-PET in brain tumours

Condition

- Metastases

Synonym
tissues and organs

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,Daniël den Hoed Foundation

Intervention

Keyword: FDG, GlucoCEST, MRI, Patients

Outcome measures

Primary outcome

GlucoCEST signal of pre-, during and post-glucose bolus injection values,

standardized uptake value (SUV), signal-to-noise-ratio (SNR),

contrast-to-noise-ratio (CNR), tumour volume, tumour perfusion

Secondary outcome

N/A

Study description

Background summary

The incidence of brain tumours is increasing. Several advanced treatments for brain tumours have resulted in improved survival, but also in an increase of treatment related effects. These may occur early (often labelled as pseudoprogression) or late (radionecrosis) and both cannot readily be distinguished from true tumour progression with magnetic resonance imaging (MRI) techniques currently available in clinical practice. Therefore, new imaging techniques are explored for better diagnosis and response assessment in patients with brain tumours but so far with limited success.
Glucose uptake and metabolism is often increased in tumours compared to normal tissue, known as the Warburg effect. This Warburg effect has been exploited in 2-[18F]-fluoro-2-deoxy-D-glucose ([18F]FDG)-positron emission tomography (PET) imaging. A recent MRI technique called glucose Chemical Exchange Saturation Transfer (glucoCEST), assesses naturally available glucose (i.e. dextrose or D-glucose) instead of FDG; therefore it has the potential to more accurately assess glucose metabolism. Previous studies have compared glucoCEST MRI to [18F]-FDG-PET in murine models on scanners with high field strength (7T or higher), showing a potential correlation between glucoCEST signal and [18F]-FDG-PET signal. In this study, we aim to compare glucoCEST MRI with [18F]FDG-PET on the PET/MRI scanner (3T) in patients with brain tumours, to increase our understanding of the component of the glucoCEST signal derived from glucose uptake. In addition, we aim to explore the clinical potential of

glucoCEST MRI in response assessment.

Study objective

The primary objective is to increase our understanding of the glucoCEST signal by comparing glucoCEST MRI to [18F]FDG-PET in patients with brain tumours on the hybrid PET/MRI scanner of the Erasmus MC. The secondary objective is to explore the clinical potential of glucoCEST MRI as routine evaluation tool for response assessment, by comparing signal differences of glucoCEST MRI to clinically used response parameters pre- and post anti-cancer treatment. The third objective is to explore which other components constitute the glucoCEST signal.

Study design

This is a single centre, non-randomised, prospective and explorative imaging study.

Study burden and risks

GlucoCEST MRI (as described in our previous METC-protocol, MEC-2020-0752) requires the insertion of two cannulae (venflons), a 3.2 minute bolus D-glucose infusion (50mL of 50% solution, through one of the two cannulae), venous blood draws (max. of 16mL, drawn from the other cannula), and MRI. Glucose infusion will induce short term hyperglycaemia, which may cause - generally minor - adverse effects: throbbing headache and a warm feeling to head and groin (feeling of miction), which last for only tens of seconds during infusion; and seldom, thrombophlebitis, which then develops within a week after placement of the cannulae.

[18F]FDG-PET requires intravenous administration of [18F]-FDG and imaging using PET, according to local protocol. An average patient of 75kg will receive 185 MBq, with an effective dose estimated at 3.6 mSv per injection. It is optional for patients to undergo dynamic PET scanning, which requires additional venous blood draws (up to 6 samples, a total of 60mL). In patients with a PET-scan scheduled for clinical purposes, the study scan will be added to that clinical scan; then, no additional dose of [18F]FDG is required for the study. Patients without a clinical PET-scan will only receive the study scan, with a single dose of [18F]FDG. However, if the treating physician believes that an additional PET-MRI scan (e.g. of thorax and abdomen) will be of clinical value for the patient, such a scan will be combined with the study scan (thereby using the same single dose of [18F-FDG]). In addition, this can potentially replace a clinical CT-scan of thorax and abdomen, thereby reducing radiation burden from CT.

The total time of glucoCEST MRI and [18F]FDG-PET imaging within the same,

single scanning session on the PET-MRI scanner, will be no longer than 90 minutes. The participants are asked to lay in the scanner during this period, which may cause discomfort for the participants.

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

• Age >= 18 years
• Primary intra-axial brain tumour of any type or secondary brain tumour (brain metastases) of any solid tumour
• Signed and dated written informed consent form prior to any study-specific procedures
• WHO performance status of 0 or 1

Exclusion criteria

• Glucose- and/or FDG-infusion related exclusion criteria:
o Uncontrolled Diabetes Mellitus type 1 or 2 (requiring fast-acting insulin)
o Uncontrolled tonic-clonic seizures (>1 per month despite anti-epileptic treatment)
• Not being able to undergo contrast enhanced MR scans or [18F]FDG-PET exam (in line with local protocol13):
o Pacemaker, mechanic heart valve, blood vessel prosthetic, stent or coil incompatible with MR scanning
o Metal in eyes (splinters, from surgery), ears (hearing aid) or on the body where it cannot be removed (e.g. insulin pump, piercings)
o Dental prosthesis with magnetic system
o Breastfeeding
o Pregnancy
o Claustrophobia
o Known anaphylactic reaction to [18F]FDG or gadolinium-based contrast agents
• Severe blood iron deficiency (with haemoglobin concentration <6.0mmol/L)
• History of severe renal disease/renal transplant, or an eGFR (MDRD) <30mL/min/1,73m2
• Has any medication that decreases the chances of obtaining reliable data and achieving the study objectives
• History of somatic or psychiatric disease/condition that may interfere with the objectives and assessments of the study

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):	01-10-2022
Enrollment:	30

Type:	Anticipated

Ethics review

Approved WMO Date:	12-10-2022
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	NL81367.078.22