GlucoCEST MRI of the brain in healthy volunteers and patients with brain tumours

Published: 25-02-2021
Last updated: 09-04-2024

To develop a protocol for glucoCEST MRI for brain using the MRI of the recently installed fully integrated PET/MRI apparatus at Erasmus MC.

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

Summary

ID

NL-OMON55021

Source
ToetsingOnline

Brief title
GlucoCEST MRI

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: GlucoCEST, Healthy volunteers, MRI, Patients

Outcome measures

Primary outcome

To optimize a glucoCEST protocol for MRI of the brain in healthy volunteers and

patients with brain tumours.

Secondary outcome

Test-retest reliability will be determined.

Study description

Background summary

Since primary brain tumours and brain metastases have an increased glucose metabolism, assessment of glucose uptake and metabolism is promising for diagnosis and response evaluation of these tumours. In clinical practice, positron emission tomography (PET) using [18F]-labeled fluorodeoxyglucose PET ([18F]-FDG) is extensively used for detection and staging of cancer, but this technique cannot be applied for intracerebral malignancies because of high physiological [18F]-FDG uptake in normal brain. Using glucose as a natural contrast agent, glucoCEST is a promising new in vivo magnetic resonance imaging (MRI) technique for assessment and quantification of glucose uptake in malignant brain tumours.

Study objective

To develop a protocol for glucoCEST MRI for brain using the MRI of the recently installed fully integrated PET/MRI apparatus at Erasmus MC.

Study design

Single center explorative diagnostic study.

Study burden and risks

Participation in this study requires bolus glucose infusion, blood draws and

imaging.
Glucose infusion will induce short term hyperglycemia, which may cause - generally minor - adverse effects: throbbing headache, warm feeling to head and groin (feeling of miction), which lasts for only tens of seconds, and thrombophlebitis. These are particularly seen with infusion times of 1 or 2 minutes. In the current protocol, the infusion time of glucose will be 3 to 4 minutes. Two intravenous cannulas will be inserted, one in each arm, one for blood draws and one for glucose infusion.
At baseline, 14,5 mL of blood will be drawn. During scanning, approximately 15,4 mL of blood will be drawn. The risk of drawing this limited amount of blood is minimal. Total scan time will be maximally 90 minutes. Subjects will be exposed to noise from the MR apparatus. Although the PET/MRI apparatus will be used, PET will not be applied. As only MRI is applied, there is no radiation burden. During the study accidental findings can occur, that can have clinical consequences (MRI-scan/abnormal blood values).

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

Healthy volunteer:
- Disease currently not requiring prescription medication
- Baseline venous glucose level below 11.0 mmol/L
- Age >= 18 years
- Signed and dated written informed consent prior to any study-specific procedures

Patient:
- WHO performance status of 0 or 1
- Baseline venous glucose level below 11.0 mmol/L
- Age >= 18 years
- Signed and dated written informed consent prior to any study-specific procedures

Exclusion criteria

Healthy volunteer:
- Glucose infusion related exclusion criteria:
* Diabetes Mellitus type 1 or 2 (self-reported or 2 measurements on separate days of a non-fasting glucose level >11 mmol/L or fasting glucose level >=7,0 mmol/L)
* Sickle cell disease or blood iron deficiency (haemoglobin concentration <9.6 g/dL = 6.0 mmol/L)
- Contra-indications for MRI exam (see the list below)
- History of seizures
- History of severe hepatic disease/liver transplant
- History of renal disease, or abnormal baseline blood sample of creatinine (31-68 µmol/L), urea (3.3-5.6 mmol/L) or eGFR (<60 mL/min)
- History of somatic or psychiatric disease/condition that may interfere with the objectives and assessments of the study

Patient:
- Glucose infusion related criteria:
* Diabetes Mellitus type 1 or 2 (self-reported or 2 measurements on separate days of a non-fasting glucose level >=11.0 mmol/L or a fasting glucose level >=7.0 mmol/L)
* Sickle cell disease or blood iron deficiency, with haemoglobin concentration <9.6 g/dL = 6.0 mmol/L)
* Has any medication that decreases the chances of obtaining reliable data and achieving the study objectives

- Contra-indications for MRI exam (see the list below)
- History of seizures
- History of severe hepatic disease/liver transplant
- History of severe renal disease/renal transplant, or abnormal baseline blood sample of eGFR (<30 mL/min)
- History of somatic or psychiatric disease/condition that may interfere with the objectives and assessments of the study

General contra-indications for MRI exam (all subjects):
* Surgery in the last 6 weeks
* Pacemaker, mechanic heart valve, blood vessel prosthetic, stent or coil
* Metal in eyes (splinters, from surgery) or ears (hearing aid) or on the body where it cannot be removed (insulin pump, piercings etc.)
* Dental prosthesis with magnetic system
* Pregnancy or breastfeeding
* Claustrophobia

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):	01-12-2020
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-02-2021

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-01-2022
Application type:	Amendment
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	NL73988.078.20