Deuterium Metabolic MRI and [18F]-flourodesoxyglucose Positron Emission Tomography for Assessment of Treatment Response Following Radioembolization of Liver Metastasis; pilot study,

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Primary objective: To assess feasability of DMI for intrahepatic tumor detection. Secondary objectives: - Head-to-head comparison between DMI and FDG-PET/CT for intrahepatic tumor detection.- Assessment of requirements for spatial resolution and...

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

Summary

ID

NL-OMON56433

Source
ToetsingOnline

Brief title
DEPLETE

Condition

- Metastases

Synonym
cancer, livermetastasis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: AMRA,NWO Perspectief Grant 2022: MAESTRO project

Intervention

Keyword: DMI, Livermetastasis, Radioembolization

Outcome measures

Primary outcome

To confirm safety and feasibility of 7T MRI scan prior to and after SIRT.

Assess the prognostic value of baseline parameters and the magnitude of

metabolic changes in 7T MRI scan. Compare technical performance of DMI to

standard-of-care FDG-PET/CT.

Secondary outcome

n.a.

Study description

Background summary

Radioembolization, a.k.a. Selective Internal Radiation Therapy (SIRT), is a liver-directed therapy for patients suffering from hepatic metastases. As SIRT is a liver-directed treatment, only patients with liver-only or liver-dominant disease are eligible for treatment. FDG-PET/CT is known to outperform conventional anatomical imaging modalities (CT or MRI) for treatment response assessment, also being of prognostic value. Subsequently following SIRT, patients are restaged with FDG-PET/CT. However, optimal timing of restaging following treatment is unknown (most commonly after 1 or 3 months, according to local institutional guidelines). More importantly, intrinsic resolution of FDG-PET/CT limits its utility in patients with small metastases, as image quality is worsened by high background noise, due to physiologic FDG uptake / metabolism in normal liver parenchyma. Additionally, FDG as radiopharmaceutical

increases additional radiation burden to patients. This study will investigate the potential of metabolic 7T MRI, non-invasively imaging metabolites using X-nuclei (e.g. 31P MRSI) and more importantly, the application of Deuterium Metabolic Imaging (DMI) with non-radioactive deuterated glucose, as a potential alternative over FDG-PET/CT.

Study objective

Primary objective: To assess feasability of DMI for intrahepatic tumor detection.

Secondary objectives:
- Head-to-head comparison between DMI and FDG-PET/CT for intrahepatic tumor detection.
- Assessment of requirements for spatial resolution and motion correction for DMI
- Confirm safety and feasibility of DMI and 31P MRSI in clinical practice
- Investigate the potential of DMI and 31P MRSI derived parameters (imaging biomarkes) for early response prediction to trans-arterial radioembolization
- Determine the most relevant time point for response assessment during clinical follow-up (1 or 3 months after treatment)

Study design

Pilot study, open-label, non-invasive, diagnostic study.

Study burden and risks

Patients will receive SIRT in clinical care, and the diagnostic, non-invasive intervention in this study will be added to routine clinical care, having no influence on treatment management. Subjects will get a 7T MRI scan thrice, which will take max. 120 min. Before or during the scan, they will receive an oral dose of deuterated glucose (20 g) dissolved in water. Deuterium (2H) is a stable, non-radioactive, isotope of hydrogen, and biologically, deuterated glucose behaves identical to normal glucose.To avoid potential hyperglycemic complications, patients suffering from diabetes mellitus are not allowed to participate. No adverse effects have been observed with oral administration of deuterated glucose at the dosage which will be used in this study. No other burden or risks are expected. Subjects will not experience direct benefits by participating in this study. However data gathered from this study may have an impact on current clinical routine, mainly defining the best time point of response assessment following SIRT. Additionally, data derived from this study will be (re)used for subsequent phase 2 imaging studies on 7T MRI scan.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adults (>=18 years)
- Referred for SIRT and deemed eligible by the multidisciplinary tumor board
- Size of at least one liver metastasis >= 1 cm on contrast enhanced CT / MRI (measurable according to RECIST 1.1) and 18FDG-avid metastatic liver disease (uptake > healthy liver uptake; measurable according to PERCIST)
- Written informed consent

Exclusion criteria

- Patients having FDG-negative disease (according to PERCIST)
- Patients with diabetes mellitus

- Patients having a general contra-indication for SIRT
- Patients with contra-indications for 7T MR scanning
- Patient unable to complete study scan (laying still for a long time)
- Patient unable or incapable to follow study proceedings

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2024
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	7T MRI
Registration:	No

Ethics review

Approved WMO

Date:	19-12-2023
Application type:	First submission
Review commission:	METC NedMec

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	NL85297.041.23