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

Published: 19-12-2023 Last updated: 02-12-2024

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**

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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  $\mathsf{DM}\mathsf{I}$ 

- 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

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# **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
- Whiten morned consen

### **Exclusion criteria**

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

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- 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         |
| Туре:                     | 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 CCMO **ID** NL85297.041.23