FAFOR

Published: 07-02-2025
Last updated: 22-05-2025

Primary Objective: to determine the dose effect relationship between radiation dose and liver function by comparing the change in liver function after SBRT in whole liver and liver sub-volumes receiving a low/medium/high doses of radiation.

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

Summary

ID

NL-OMON57540

Source
Onderzoeksportaal

Brief title
FAFOR

Condition

- Metastases

Synonym
patients with a single liver metastasis

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek (AVL)
Source(s) of monetary or material Support: Derde geldstroom (anders, zoals collectebussenfondsen, Europese Unie, vakministeries of bedrijven)

Intervention

- Other intervention

Explanation

N.a.

Outcome measures

Primary outcome

To determine the change in liver function after SBRT in whole liver and regional liver function sub-volumes receiving a low/medium/high dose by measuring the hepatic mebrofenin uptake rate (MUR) divided by the body surface area (BSA) before and 3-4 months after SBRT.

Secondary outcome

not applicable

Study description

Background summary

In this study, we aim to determine the dose-effect relationship between radiation dose and liver function by performing a HEBIS scan before and after SBRT. HEBIS is a nuclear imaging technique that uses [99mTc]Tc-mebrofenin to quantitatively assess liver function. HEBIS better predicts the risk of postsurgical liver failure compared to volumetry alone and is implemented in clinical practice before surgery.

To prevent liver failure after SBRT, current clinical dose constraints require that ≥ 700 ml of normal liver should receive less than 15 Gy in 3 fractions. The exact local dose-effect relation is however unknown. Doses below 15 Gy are still damaging [Pursley, 2020], while liver tissue receiving doses above 15 Gy will retain some function [Howells, 2012].

By associating the 3D radiation dose distribution with the HEBIS scan, we can evaluate the impact of radiation dose on liver function for different dose levels. This analysis will refine existing dose-effect relationships, enabling more tailored treatment of liver metastases in the future.

Study objective

Primary Objective: to determine the dose effect relationship between radiation dose and liver function by comparing the change in liver function after SBRT in whole liver and liver sub-volumes receiving a low/medium/high doses of radiation.

Study design

This single-center study will be conducted at the NKI-AVL and follows the design of a prospective diagnostic pilot study.

Intervention

HEBIS-scan

Study burden and risks

Participation in this study has no adverse consequences or risks. However, the study does require additional time, as two HEBIS scans will be performed. For the HEBIS scans, an intravenous line (IV) will need to be placed, which may cause some pain, bruising, or (in rare cases) an infection. Additionally, the study involves the use of a radioactive substance and a SPECT-CT scan (the HEBIS scan), which involves exposure to X-ray radiation."

Contacts

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Trial sites

Trial sites in the Netherlands

Antoni van Leeuwenhoek (AVL)
Target size: 15

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient treated for a liver metastasis with SBRT with treatment prescription of 3 x 20 Gy.
- Age ≥ 18 years
- Able to provide signed written informed consent prior to any study specific procedure

Exclusion criteria

- WHO > 2
- Pregnancy
- Prior radiation therapy of the liver
- Lactation, unable to substitute for 24 hours
- Inability to cooperate with the scan process: inability to lie relatively still and in supine for 30-60 minutes or patient body habitus above scanner dimensions
- Exclusion criteria for HEBIS scan:
    - GFR < 30 ml/min/1.73m2
    - < 2 weeks after antiviral eradication therapy for hepatitis C
    - Bilirubine > 30 µmol/l
    - Relative contra-indications (possibly affecting liver function): opiates, barbiturates, somatostatine, colestyramine, rifampicine, atropine.

Study design

Design

Study phase:	N/A
Study type:	Observational invasive
Intervention model:	Single

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Dose-response

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2025
Enrollment:	15
Duration:	4 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: No

Plan description
N.a.

Ethics review

Approved WMO

Date:	20-05-2025
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
Research portal	NL-009268