IXSI safety study

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23992

Source
Nationaal Trial Register

Brief title
IXSI

Health condition

hepatocellular carcinoma / liver metastases

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: ERC

Intervention

Outcome measures

Primary outcome

Primary Objective:
• To establish the safety of acquiring 2D and 3D hybrid images using IXSI in an interventional setting.

Secondary outcome

Secondary Objectives:

• To establish the clinical usability of dosimetry based on interventional SPECT/CBCT using IXSI compared to traditional SPECT/CT based dosimetry after the pretreatment procedure.
• To image the (hemo-)dynamic processes influencing the microsphere distribution during the administration of 99mTc-MAA, using IXSI.

Study description

Background summary

Radioembolisation is a clinically accepted oncological treatment for unresectable liver tumours. It involves x-ray and nuclear imaging guided injection of radioactive microspheres into the hepatic artery through a catheter. Current clinical protocol, as advised by the vendors of the microspheres, involves a pretreatment safety procedure using 99mTc-MAA particles, that are injected at the intended therapy location during an extra procedure prior to the therapy procedure. After this pretreatment procedure, but before the start of the therapy, diagnostic nuclear scintigraphy and a SPECT/CT are acquired to rule out excessive lung shunting, shunting to other organs and to assess microsphere distribution in the liver for dosimetry based therapy planning. For this nuclear imaging the patient is transferred to the nuclear medicine department. Limitations of the current workflow include length of the total treatment, and the inaccuracies introduced by replacing the catheter during treatment in the exact same location as during the pretreatment procedure. Introduction of a novel mobile hybrid C-arm (IXSI), capable of real time x-ray and nuclear imaging and of SPECT/CBCT imaging during the intervention, may shorten the treatment to a single radioembolisation procedure, and ensure the same catheter location during pretreatment and treatment injections. In addition, the availability of hybrid imaging during the intervention may help to optimise treatment by direct dosimetric feedback.

The department of radiology at UMC Utrecht initiated a diagnostic C-arm capable of acquiring simultaneous and real-time x-ray and nuclear images to be used in the intervention room. Innovative aspects include a newly developed dual modality SPECT/CBCT detector that allows for combining x-ray and nuclear imaging in a compact and simultaneous manner and the design of a mechanical mobile gantry that can circle the patient in a close body contouring orbit and that allows for integration in an existing intervention room. Using a non-clinical prototype in phantom studies, it has been demonstrated that it is feasible to acquire simultaneous and real-time nuclear and hybrid images. The desire is to demonstrate the hybrid imaging capabilities of IXSI in an explorative pilot study in the intervention room. The study aims at demonstrating that applying IXSI improves clinical practice.

The primary objective of the study is to establish a safe application of IXSI for obtaining 2D and 3D hybrid images in an interventional setting. To this end, for 12 to 15 selected subjects the 99mTc-MAA scout procedure will be extended by additional scans made by IXSI. Angiographic work-up will be identical to the standard procedure up to the point of 99mTc-MAA injection. Then, 2D imaging of the controlled injection of 99mTc-MAA using IXSI is performed, followed by the acquisition of a SPECT/CBCT of the liver by IXSI.

In addition to radioembolisation, a number of other applications for IXSI are envisioned, including the guidance of sentinel lymph node procedures, guidance of biopsies, and inclusion of functional information during cardiac interventions.

Study objective

Primary Objective:
The main study parameter is to establish the safety of the use of IXSI in an interventional setting. Safety will be assessed based on the CTCAE methodology. Use of IXSI will be considered safe in the absence of Adverse Device Effects (ADE's).

Study design

Patients will come to the clinic for their regular pretreatment procedure. Angiographic work-up will be identical to the standard procedure up to the point of 99mTc-MAA injection. For the interventions of the IXSI study the patient will spend an additional 30-90 minutes in the angio suite. The 2D and 3D images obtained using IXSI will be examined.

Intervention

Angiographic work-up will be identical to the standard procedure up to the point of 99mTc-MAA injection. Then, 2D imaging of the controlled injection of 99mTc-MAA using IXSI is performed, followed by the acquisition of a SPECT/CBCT of the liver and lungs by IXSI.

Contacts

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Eligibility criteria

Inclusion criteria

Participants will be recruited from patients, which are clinically selected to undergo a radioembolisation treatment at the UMC Utrecht. This will be adult men and women with liver tumour(s), that have no curative treatment options. The patient's indication for hepatic radioembolisation will be discussed in a multidisciplinary tumour board.

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Participants must have given written informed consent and comply with the re-quirements of the study protocol.
2. Must be aged 18 years or over.
3. Must be selected to undergo a 99mTc-MAA procedure as part of their radioembolisa-tion treatment.
4. Sufficiently fit to undergo an additional examination time of 30-90 minutes.
5. Have a CT acquired less than 6 weeks before the pretreatment radioembolisation procedure.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Patients expected to require more than two injection positions for radioembolisa-tion treatment.
2. Pregnancy or nursing.
3. Patients suffering from psychic disorders that make a comprehensive judgement impossible, such as psychosis, hallucinations and/or depression.
4. Patients who are declared incompetent.
5. Previous enrollment in the present study
6. Claustrophobia
7. The last dose of prior chemotherapy has been received less than 4 weeks prior to the planned 99mTc-MAA pretreatment procedure.
8. Radiation therapy within the last 4 weeks before the planned 99mTc-MAA pretreat-ment procedure
9. Major surgery within the last 4 weeks prior to the planned 99mTc-MAA pretreatment procedure
10. Any unresolved toxicity greater than Common Terminology Criteria for Adverse Events (CTCAE version 5, see appendix A) grade 2 from previous anti-cancer treatment
11. Body weight over 250 kg (because of maximum table load)
12. Patient length over 1.90 m (to fit IXSI geometry)
13. Patient bust line over 135 cm (to fit IXSI geometry)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2021
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8927
Other	METC Utrecht : METC 20/816

Study results

Summary results

1. van der Velden S, Kunnen B, Koppert WJC, et al. A Dual-layer Detector for Simultaneous Fluoroscopic and Nuclear Imaging. Radiology. 2019;290(3):833-838. https://doi.org/10.1148/radiol.2018180796.
2. Dietze MMA, Kunnen B, van der Velden S, et al. Performance of a dual-layer scanner for hybrid SPECT/CBCT. Phys Med Biol. 2019;64(10):105020. http://dx.doi.org/10.1088/1361-6560/ab15f6.
3. Dietze MMA, Kunnen B, Brontsema F, et al. A Compact and Mobile Hybrid C-arm Scanner for Simultaneous Nuclear and Fluoroscopic Image Guidance. Submitted to Eur. Radiol. Aug 2020