IXSI: Interventional X-ray and Scintigraphy Imaging of 99mTc-MAA during the radioembolisation pretreatment procedure

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Primary objective: To establish the safety of acquiring 2D and 3D hybrid images using IXSI in an interventional setting. Secondary objectives: To evaluate dosimetry of SPECT/CBCT acquired by IXSI. To image the (hemo-)dynamic processes influencing…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON55138

Source
ToetsingOnline

Brief title
IXSI

Condition

- Hepatic and hepatobiliary disorders

Synonym
liver tumor

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: ERC grant. Grant Agreement number 646734

Intervention

Keyword: C-arm, Hybrid imaging, Radioembolisation, SPECT/CBCT

Outcome measures

Primary outcome

Safety of the use of IXSI in an interventional setting.

Secondary outcome

Comparison of dosimetry (lung shunt fraction (LSF), tumour to non-tumour ratio

(T/N ratio) and dose to liver segments) based on IXSI and conventional

SPECT/CT.

Visual inspection of 2D images of 99mTc-MAA administration.

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

Study objective

Primary objective: To establish the safety of acquiring 2D and 3D hybrid images using IXSI in an interventional setting.
Secondary objectives: To evaluate dosimetry of SPECT/CBCT acquired by IXSI.
To image the (hemo-)dynamic processes influencing the distribution of 99mTc-MAA using hybrid 2D images acquired by IXSI.

Study design

First in man, safety study

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.

Study burden and risks

The patients that participate in this study will spend more time in the intervention room for the pre-treatment procedure. It is anticipated that the imaging performed by IXSI will take an additional 30 to 60 minutes on top of the regular procedure time (regular procedure time ranges from 1.5 to 3.5 hours). During imaging with IXSI the patient will receive additional dose from the fluoroscopy and from the low dose CBCT acquired for the SPECT/CBCT. The additional dose area product (DAP) will be in the range of 0.23 to 7.1 mGy ·m2, depending on the kV and mA settings used during procedure. For reference, current 99mTc-MAA procedure delivers a mean DAP of 31 mGy·m2, ranging from 5.6 mGy·m2 to 77 mGy·m2 (based on 99mTc-MAA procedure of 20 patients). Furthermore, these patients are all scheduled for a treatment using radiation. The treatment dose is at least three orders of magnitude higher than the additional dose delivered by IXSI.
This study will have a limited impact on the standard radioembolisation treatment since catheter placement is still performed using the Allura (standard clinical c-arm used for guidance of radioembolisation procedures) and patients will still receive their clinical SPECT/CT at the nuclear medicine department. All medical decisions are based on the standard forms of imaging and the treating physician is blinded to the images produced by IXSI.

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

1. Participants must have given written informed consent and comply with the requirements 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 radioembolisation 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 pre-treatment radioembolisation procedure.

Exclusion criteria

1. Patients expected to require more than two injection positions for radioembolisation 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 pretreatment 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 1) 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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2021
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	IXSI
Registration:	No

Ethics review

Approved WMO Date:	12-02-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	20-05-2021
Application type:	Amendment
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	NL71365.041.20