Clinical validation of a fractional administration device for holmium-166 microspheres during selective internal radiation therapy in patients with liver tumours

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To investigate the in vivo performance and safety of a novel medical device for the injection of holmium-166 microspheres during SIRT. This main potential advantage of this device is that it allows for injection of a during treatment determined dose...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON50197

Source
ToetsingOnline

Brief title
CONTROL

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
liver cancer, liver metastases

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: bedrijven ,Terumo

Intervention

Keyword: holmium-166, radioembolization, SIRT

Outcome measures

Primary outcome

To determine technical performance and accuracy of a novel injection device for SIRT. Additionally, the safety of the device will be assessed.

Secondary outcome

To perform dosimetry based on MRI and SPECT imaging of holmium-166 and correlate this to tumour response. To investigate the potential added value of gated 166Ho-SPECT/CT compared to conventional 166Ho-SPECT/CT . To investigate the added value of a novel reconstruction algorithm for cone-beam CT (CAVAREC) that compensates for motion during CT acquisition. Local response evaluation at 3 months after treatment through contrast-enhanced MRI and/or contrast-enhanced CT, according to mRECIST/RECIST 1.1 criteria (depending on tumour type).

Study description

Background summary

Selective internal radiation therapy (SIRT) is a treatment for liver cancer during which radioactive microspheres are injected into the hepatic artery through a catheter under x-ray fluoroscopy image-guidance. These microspheres are transported with the blood flow through the liver, until they get stuck in the arterioles because of their size. This is currently not a real-time controlled procedure, and the achieved distribution of the microspheres is only verified days after treatment, without any consequences in case of a failed

treatment. The holmium-166 loaded microspheres used in this study can be visualized with MRI. In the EMERITUS-study, we demonstrated the feasibility of visualising the microsphere distribution during treatment already, potentially allowing for MRI-guided treatment. Another prerequisite for image-guided treatment is the ability to administer a precise, on-site determined amount of microspheres. For this purpose, a novel injection device has been developed, that will be validated in this clinical study.

Study objective

To investigate the in vivo performance and safety of a novel medical device for the injection of holmium-166 microspheres during SIRT. This main potential advantage of this device is that it allows for injection of a during treatment determined dose, which is not possible with the current administration tool.

Study design

The study design is very similar to the recently completed EMERITUS-1 study. Patients will be treated as per usual, except that the administration of microspheres will be performed while the patient is positioned in the bore of an MRI scanner. Microspheres will be injected using a novel device, however, the total injected dose and therefore treatment efficacy will be identical to treatment outside of the study.

Intervention

Holmium-166 SIRT as per usual, with patient positioned in MRI scanner. Injection of microspheres will be done with a novel injection device.

Study burden and risks

It is anticipated that treatment with radioactive microspheres will reduce tumour size and will improve quality of life as known from literature from holmium-166 and yttrium-90 SIRT. Treatment consist of injecting an identical dose of microspheres as usual, and therefore, no differences in treatment efficacy are expected. The additional burden consists of treatment taking place at the MRI-scanner instead of the angio suite, as a result of which treatment will take approximately 60-90 minutes longer than usual.
For treatment within this study, a total of 8 visits (one is a telephone call) is required, all of which are part of regular patient care. Multiple diagnostic scans will be performed outside regular patient care, with modalities using non-ionizing radiation. If the new injection device performs as expected, follow-up studies will investigate a more personalized treatment for future cohorts, likely resulting in more effective treatment.

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. Diagnosis of hepatocellular carcinoma or liver metastases originating from colorectal cancer
2. At least one lesion of 10 mm in the longest diameter on contrast-enhanced MRI or contrast-enhanced CT
3. Patient is eligible for SIRT as determined by the tumour board (in Dutch: MDO)
4. Patient has a life expectancy of 12 weeks or longer
5. Patient has a WHO performance score of 0-2

Exclusion criteria

1. Significant extrahepatic disease (2x sum of diameters of lesions outside the liver > sum of lesions inside the liver)
2. Radiation therapy, chemotherapy or major surgery within 4 weeks before treatment
3. Serum bilirubin > 2.0 x the upper limit of normal
4. ALAT, ASAT, alkaline phosphatase (AF) > 5x the upper limit of normal
5. Glomerular filtration rate (GFR-MDRD) <35 ml/min
6. Leukocytes <4.0 * 10^9/L or platelet count <60 * 10^9/L
7. Significant heart disease that in the opinion of the physician increases the risk of ventricular arrhythmia.
8. Pregnancy or breast feeding
9. Disease with increased chance of liver toxicity, such as primary biliary cirrhosis or xeroderma pigmentosum
10. Patients ineligible to undergo MR-imaging (claustrophobia, metal implants, etc)
11. Portal vein thrombosis of the main branch (more distal branches are allowed)
12. Evidence of clinically relevant, untreated grade 3 portal hypertension
13. Untreated, active hepatitis
14. Body weight > 150 kg (because of maximum table load)
15. Severe allergy for i.v. contrast (Iomeron, Dotarem and/or Primovist)
16. Lung shunt > 30 Gy, as calculated using scout dose holmium-166 SPECT/CT
17. Uncorrectable extrahepatic deposition of scout dose activity. Activity in the falciform ligament, portal lymph nodes or gallbladder are accepted.

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):	30-06-2022
Enrollment:	6

Type:	Actual

Medical products/devices used

Generic name:	fractional administration device
Registration:	No

Ethics review

Approved WMO Date:	30-11-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-01-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL78931.091.21