The RALLY study: dose finding study for radiation lobectomy using holmium-166 microspheres to improve resectability in patients with HCC.

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Holmium-166 radiation lobectomy is a safe method to bridge patients with HCC to resection.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23909

Bron
Nationaal Trial Register

Verkorte titel
RALLY

Aandoening

Hepatocellular Carcinoma

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: Terumo

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To establish the maximum tolerated healthy liver-absorbed dose of 166Ho-microspheres in patients with HCC who receive radiation lobectomy as a bridge to surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

Radiation lobectomy as a means of controlling tumour growth while concomitantly inducing future liver remnant (FLR) hypertrophy has recently gained interest to convert unresectable hepatocellular carcinoma (HCC) patients. Dosimetry is of major importance here, since particularly healthy liver-absorbed dose drives FLR response. However, current techniques using yttrium-90 (90Y) beta-radiation emitting microspheres cannot be visualised properly. This makes it difficult to accurately predict healthy liver-absorbed dose. Radiation lobectomy using holmium-166 (166Ho) offers a potentially more safe, effective and personal treatment modality, due to its variety of imaging options. However, the acceptable toxicity dose profile of 166Ho on healthy liver tissue in this setting is unknown.

Doel van het onderzoek

Holmium-166 radiation lobectomy is a safe method to bridge patients with HCC to resection.

Onderzoeksopzet

T1: Screening
T2: Radiation lobectomy
T3: Post radition lobectomy follow-up visits (at 1.5, 3, 4.5, 6 and 9 months after radiation lobectomy or until resection is feasible).
T4: Surgery
T5: Post surgery follow-up visit (3 months after surgery)

Onderzoeksproduct en/of interventie

Holmium-166 radiation lobectomy

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study (including the biobank), a subject must meet all of the following criteria:

1) Patients must have given written informed consent.
2) Age ≥ 18 years.
3) ECOG Performance status 0-1.
4) Diagnosis of HCC, established according to the Netherlands HCC guideline criteria (in line with American AASLD criteria): nodule >1 cm in a patient at risk for HCC, with combination of arterial hypervascularity and venous or delayed phase wash-out on multiphase CT-scan or MRI-scan.
5) HCC with indication for major hepatectomy (i.e., >2 segments), as decided by multidisciplinary tumour board.
6) Hepatobiliary scintigraphy > 1.5%/min/m2 and < 2.7 %/min/m2.
7) Negative pregnancy test for women of childbearing potential. Female patients of childbearing potential should use a highly effective acceptable method of contraception (oral contraceptives, barrier methods, approved contraceptive implant, long-term injectable contraception, intrauterine device or tubal ligation) or should be more than one year postmenopausal or surgically sterile during their participation in this study (from the time they sign the consent form), to prevent pregnancy.
8) Patients with compensated Child-Pugh A and unilobar BCLC-B or less (without evidence of portal hypertension).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1) Evidence of extrahepatic disease (MRI-scan liver and multiphase abdominal CT as well as a thoracic CT are routinely performed at screening).
2) Any previous hepatic external beam radiation therapy before the start of study therapy.
3) Previous treatment with radioembolization/radiation lobectomy.
4) Major surgery within 4 weeks or incompletely healed surgical incision before starting study therapy.
5) Glomerular filtration rate <35 ml/min, determined according to the Modification of Diet in Renal Disease formula.
6) Non correctable INR > 1.5.
7) Significant cardiac event (e.g., myocardial infarction, superior vena cava syndrome, New York Heart Association (NYHA) classification of heart disease ≥ 2 within 3 months before entry, or presence of cardiac disease that in the opinion of the investigator increases the risk of ventricular arrhythmia.
8) Pregnancy or breastfeeding.
9) Patients suffering from psychic disorders that make a comprehensive judgment impossible, such as psychosis, hallucinations and/or depression.
10) Patients who are declared incompetent.
11) Previous enrolment in the present study.
12) Patients who do not use an acceptable method of contraception during their participation in this study (from the time they sign the consent form) to prevent pregnancy. In case of female: are less than 1 year postmenopausal and not using an acceptable method of contraception. Patients who had surgical sterilization may be included.
13) Any contraindication precluding surgery, with the exception of insufficient FLR as defined by hepatobiliary scintigraphy.
14) Portal vein thrombosis (tumour and/or bland) (diagnosed on contrast enhanced transaxial images).
15) Untreated active hepatitis. In case of detectable viral hepatitis B virus load, treatment with a nucleos(t)ide analog such as entecavir or tenofovir should be instituted.
16) Transjugular intrahepatic portosystemic shunt.
17) Body weight over 150 kg (because of maximum table load).
18) Severe allergy for intravenous contrast (Visipaque®).
19) Lung shunt > 30 Gy, as calculated using 166Ho-microspheres scout dose using SPECT/CT.
20) Not correctable extrahepatic deposition of scout dose activity. Activity in the falciform ligament, portal lymph nodes and gallbladder is accepted.
21) Any systemic therapy (including transcatheter arterial chemoembolization) prior to the start of study therapy. Radiofrequency ablation or previous resection (> 4 weeks) is accepted.
22) Leukocytes <2 109/L and/or platelet count <50 109/L. Serum bilirubin >34.2 micromol/L (2 mg/dL).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-09-2021
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	15-09-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54237
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8902
CCMO	NL75713.041.21
OMON	NL-OMON54237

Resultaten