Combination of locally administered radiotherapy and thermal tumour destruction for treatment of liver metastases originated from primary bowel cancer

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29581

Source
Nationaal Trial Register

Brief title
The RELAPSE study

Health condition

Colorectal liver metastases, Recurrence, Radiofrequency ablation, Radioembolization

Sponsors and support

Primary sponsor: Prof. Dr. R. van Hillegersberg
University Medical Center Utrecht
Department of Surgery
Source(s) of monetary or material Support: Not confirmed yet

Intervention

Outcome measures

Primary outcome

Local Liver Recurrence Rate (defined as radiologic detection of residual or recurrent viable tumor which is related to the ablation zone, located in the same segment as the treated lesion)

Secondary outcome

Treatment related adverse events

Intrahepatic recurrences

Study description

Background summary

Radiofrequency ablation (RFA) permits an alternative treatment option for patients with irresectable colorectal liver metastases (CRLM). However, local liver recurrence is a frequent phenomenon, which jeopardizes disease free survival (DFS) of these patients. The rate of liver recurrence confined to the liver is up to 60%1, whereas after liver surgery, liver only recurrence is reported in approximately 30 to 35% of patients 2, 3. Experimental data demonstrated a stimulating effect of RFA on the outgrowth of remaining tumor cells surrounding the lesion4. Selective internal Yttrium-90 (Y-90) radioembolization is a form of brachytherapy in which radioactive microspheres are injected into the hepatic artery in order to destroy malignant tissue. A combination therapy of RFA and radioembolization may therefore reduce the local liver recurrence rate and prolong DFS in patients with CRLM. In this study we will assess the feasibility of this approach in patients with CRLM treated with Y-90 radioembolization after RFA.

Objectives: Primary objective is to assess the efficacy of RFA in combination with Y-90 radioembolization in patients with CRLM.
Secondary objectives are: assessment of occurrence of any treatment related adverse events following RFA in combination with Y-90 radioembolization in patients with CRLM and intrahepatic recurrences within 12 months after the RFA procedure.

Study design: Multicenter, phase II prospective cohort study.

Study population: Patients ¡Ý 18 years of age with CRLM, who previously received potentially curative surgery of the primary tumor (R0) and will undergo radiofrequency ablation for treatment of colorectal liver metastases with a maximum diameter of 5 cm and maximum number of 5 lesions.

Intervention: Patients will undergo RFA followed by Y-90 radioembolization. To allow for liver regeneration, radioembolization will take place one month after the RFA procedure.

Main study parameters/endpoints: Primary endpoint of the study is the local liver recurrence rate after 12 months of follow-up (the local liver recurrence). Secondary endpoints are the occurrence of any treatment related adverse event within 30 days after the Y-90 radioembolization procedure and intrahepatic recurrences.

Study objective

By combining Yttrium-90 radioembolization and Radiofrequency Ablation for treatment of patients with colorectal liver metastases, we might be able to target the remnant tumour cells in the rim of the ablation zone and improve the disease free survival of the patients.

Study design

The local liver recurrence and the intrahepatic recurrence rate rate will be assessed 12 months after the RFA procedure.

Treatment related adverse events will be assessed by the percentage of adverse events occurring within 30 days after the radioembolization procedure.

Intervention

The standard treatment is Radiofrequency Ablation (RFA) for colorectal liver metastases (CRLM). Patients will not be randomized. All patients will additionally be treated with Yttirum-90 Radioembolization, one month after the RFA procedure. The RFA procedure can be performed percutaneously, laparoscopically or during an open procedure. The duration of the RFA procedure depends on the surgical approach and the number of the lesions. One or two weeks prior to the radioembolization procedure, each patient will undergo pre-procedural screening by means of hepatic angiography and subsequently technetium-99m-labelled albumin macroaggregates (99mTc-MAA) injection, followed by planar imaging and Single Photon Emission Computed Tomography (SPECT). The pre-procedural angiography permits visualization of the anatomy of the vessels and provides an opportunity to embolize arteries if necessary (to spare the gastric and duodenal arterial flow from incorporating radioactive spheres). The 99mTc-MAA and the subsequent nuclear imaging will determine the presence of any shunts from the hepatic arterial system to the pulmonary or gastrointestinal venous systems. Both the pre-procedural screening and the radioembolization procedure will take about 2 tot 3 hours depending on the hepatic vascular anatomy. Patients will be admitted the day before the procedure and discharged the day after the procedure.
The main study parameter is the local liver recurrence rate after RFA combined with Yttrium-90 radioembolization for patients with CRLM. This will be assessed by the number and percentage of patients with local liver recurrence, 12 months after the RFA procedure. Local liver recurrence is defined as: radiologic detection of residual or recurrent viable tumor which is related to the ablation zone, located in the same segment as the treated lesion.

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Eligibility criteria

Inclusion criteria

1.Patients who have signed written informed consent;

2.Patients undergoing open, laparoscopic or percutaneous RFA treatment;

3.Aged 18 years or older;

4.ECOG performance status of 0-2;

5.Subjects with at least one and a maximum of five measurable lesion according to the RECIST criteria (5.0 cm or smaller in axial plane) on pre-operative imaging;

6.Normal renal and liver function tests at baseline (as described above).

Exclusion criteria

1.Irresectable extrahepatic metastases;

2.Liver resection;

3.Pregnant or breast-feeding patients;

4.Any form of chemotherapy within 2 months prior to the Y-90 radioembolization;

5.Exclusion criteria of radioembolization:

- Compromised main portal vein;

- Uncorrectable extrahepatic shunting to the gastrointestinal tract;

- Unacceptable shunting to the lungs.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2013
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 41502
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3852
NTR-old	NTR4012
CCMO	NL42401.041.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41502

Study results

Summary results
N/A