Radioembolization for Colorectal Liver Metastases after Ablation: a Prospective study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41502

Source
ToetsingOnline

Brief title
The RELAPSE study

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
'Colorectal liver metastases' and 'liver cancer disseminated from the colon'

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,KWF grant

Intervention

Keyword: Ablatie, Radioembolization, Radiofrequency ablation, Yttrium-90

Outcome measures

Primary outcome

Primary endpoint of the study is the local liver recurrence rate after 12

months of follow-up (the local liver recurrence)

Secondary outcome

Secondary endpoints are the occurrence of any treatment related adverse event

within one month after the Y-90 radioembolization procedure, intrahepatic

recurrences and quality of life.

Study description

Background summary

Ablation therapy 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%, whereas after liver surgery, liver only recurrence is reported in approximately 30 to 35% of patients. Experimental data demonstrated a stimulating effect of ablation on the outgrowth of remaining tumor cells surrounding the lesion. 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 of ablation therapy 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 ablation.

Study objective

Primary objective is to assess the efficacy of ablation therapy in combination

with Y-90 radioembolization in patients with CRLM.
Secondary objectives are:
1) Assessment of occurrence of any treatment related adverse events following ablation in combination with Y-90 radioembolization in patients with CRLM.
2) Intrahepatic recurrences within 12 months after the ablation procedure.
3) To assess the impact of Y-90 radioembolization additional to the ablation therapy on the quality of life of patients.

Study design

The proposed study is a multicenter, phase II prospective cohort study.

Intervention

Patients will undergo radiofrequency ablation or microwave ablation followed by Y-90 radioembolization.

Study burden and risks

Combining Y-90 radioembolization with ablation therapy requires pre-procedure screening and four nights of extra hospitalization in two sessions. Although minimally invasive, Y-90 radioembolization is not without adverse events. Related adverse events are symptoms of the post-embolization syndrome and in general, these symptoms emerge within 24 hours post-procedure and fade within 5 to 7 days. Grade II clinical adverse events were reported in 68% of patients and grade III toxicities in 6% of patients. Grade II and grade III biochemical adverse events were reported in respectively 16% and 2% of patients. Most adverse events can be treated when necessary and for severe adverse events, clinical guidelines are determined in order to minimize the occurrence of these events. The addition of Y-90 radioembolization to ablation in treatment of patients with CRLM may decrease the recurrence rate, which could be an important step towards increased survival of these patients.

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. Patients who have signed written informed consent
2. Patients undergoing open, laparoscopic or percutaneous ablation therapy
3. Age * 18 years
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 in axial plane) on pre-operative imaging
6. Normal renal and liver function tests at baseline

Exclusion criteria

1. Irresectable extrahepatic metastases
2. Ablation procedure combined with 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 phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	16-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-04-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	06-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29581
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL42401.041.12
OMON	NL-OMON29581