

Microscopic and macroscopic liver tumor dimensions assessed with pathology and MRI studies to establish safety margins for stereotactic body radiation therapy: a pilot study.

Published: 15-01-2009

Last updated: 05-05-2024

- To measure the microscopic infiltration depth around colorectal liver metastases.- To correlate pathologic macroscopic/microscopic tumor dimensions with MR imaging findings.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON32597

Source

ToetsingOnline

Brief title

Microscopic and macroscopic liver tumor dimensions

Condition

- Metastases

Synonym

liver metastases in patients with colorectal cancer

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: metastases, MRI, safety margins, stereotactic body radiation therapy

Outcome measures

Primary outcome

- Microscopic tumor infiltration depth
- Correlation between pathology and MRI

Secondary outcome

not applicable

Study description

Background summary

Colorectal cancer is one of the most prevalent cancers and leading cause of cancer mortality worldwide. As many as 50-70% of patients diagnosed of colorectal cancer will present liver involvement during follow-up, being the only site of recurrence in half of these patients. Surgery is accepted as a potentially curative option with survival rates at 5 years of 25-35% for liver metastases when disease is confined to the liver. However, the majority of patients are not eligible for surgery because of diminished liver function capacity after several resections or concomitant medical diseases. For patients who are not suitable for surgery, other local treatment methods, especially radiofrequency ablation (RFA) are emerging as alternative curative options but, proximity of the lesion to the gallbladder or the main vessels constitute major problems to apply this treatment. Radiotherapy has become a potential new treatment option for primary and metastatic liver tumors around the world.

Study objective

- To measure the microscopic infiltration depth around colorectal liver metastases.
- To correlate pathologic macroscopic/microscopic tumor dimensions with MR

imaging findings.

Study design

This will be a prospective cohort pilot study. In total 40 colorectal liver metastases will be included: 20 specimens treated preoperatively with chemotherapy and 20 not. The estimation to complete the study is half a year.

Study burden and risks

The burden associated with participation is the burden associated with the acquirement of a MRI scan with intravenous contrast agent administration. The total scan will take 60 - 90 minutes to obtain. The subjects who will be asked for their participation will not benefit from the results of this study unless they will become eligible for stereotactic body radiation therapy in the future. The study however can only be done with the cooperation of this patient group.

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

Patients with liver metastases of colorectal cancer planned for surgical treatment.

Exclusion criteria

- Patients who are not suited for a MRI scan.
- Patients with insufficient renal function (estimated creatinine clearance < 50 ml/min)

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-02-2009

Enrollment: 40

Type: Actual

Ethics review

Approved WMO

Date: 15-01-2009

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL25359.078.08