Mri-Assisted high intensity focused ultrasound metastatic Liver Tumor Ablation (MALTA study)

Published: 12-03-2014
Last updated: 19-03-2025

This trial will be a first-in-man study. It should therefore demonstrate the feasibility and accuracy of liver tumor ablation. Since image-guided tumor ablation techniques, such as MR-HIFU, leave the coagulated tumor in situ, treatment accuracy is...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41228

Source
ToetsingOnline

Brief title
MALTA

Condition

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

Synonym
Colerectal liver cancer; liver cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Center for Translational Molecular Medicine (CTMM)

Intervention

Keyword: Ablation Techniques, Colorectal liver metastases, High-Intensity Focused Ultrasound Ablation, Interventional MRI

Outcome measures

Primary outcome

The primary objective of this first-in-man study is to investigate the accuracy of MR-HIFU ablation of metastatic liver tumors. The accuracy is assessed by comparing: I) ablated tissue volume, visualized as non-perfused volume on contrast-enhanced MR imaging after HIFU treatment; II) thermal dose as measured by MR thermometry during treatment; III) the necrotic tissue volume in the surgical resection specimen. In addition, the quality of the ablated tissue volume will be assessed.

Thus, complete tumor ablation is not required for this study; tumor size is therefore of lesser importance.

Secondary outcome

To assess the safety of MR-HIFU liver tumor ablation in the patient population as described in chapter 6.1. Therefore, I) any minor or major complications will be recorded; and III) liver function tests (LFTs) in blood plasma will be measured before and after the procedure and before surgical resection of the tumor (to assess the biochemical effects of MR-HIFU liver tumor ablation).

In addition, it is important to collect data regarding patient eligibility for MR-HIFU treatment. Patients can be considered not eligible for the MR-HIFU procedure based on computer treatment simulations. These simulations are

performed using the pre-treatment MRI scan that patients undergo approximately one week before treatment (see also chapter 3.2). For each patient that participates in the study but is considered ineligible for the MR-HIFU procedure, the reason will be recorded on a screening and enrollment log and on the CRF.

Study description

Background summary

Metastatic liver cancer represents a significant disease burden in the western world. Unfortunately, only a minority of patients is eligible for surgical resection. Therefore, most patients have to rely on alternative treatment options for improved survival and quality of life. Since sustained quality of life is very important for patients with metastatic cancer, minimally- and non-invasive treatment options are of particular interest. Magnetic resonance-guided high intensity focused ultrasound (MR-HIFU) allows for image-guided, non-invasive tumor ablation. Due to the non-invasiveness of this technique, it can potentially improve survival of metastatic liver cancer patients while retaining quality of life in the palliative phase.

Study objective

This trial will be a first-in-man study. It should therefore demonstrate the feasibility and accuracy of liver tumor ablation. Since image-guided tumor ablation techniques, such as MR-HIFU, leave the coagulated tumor in situ, treatment accuracy is of paramount importance. This study was therefore designed as a treat-and-resect study, in order to validate the accuracy of tissue ablation with histopathology. This also means that complete tumor ablation is not required, since we aim to study the accuracy of the ablated tissue volume, not the possibility to completely ablate the tumor.

Study design

This feasibility study is designed as a single-center, single arm, non-randomized treat-and-resect trial to evaluate the treatment accuracy and safety of MR-HIFU in patients with metastatic liver tumors.

Intervention

MR-HIFU is used to ablate (part of) one metastatic liver tumor. HIFU ablation uses focused ultrasound waves to non-invasively heat and thermally ablate tissue. MR guidance is used for treatment planning, treatment monitoring (temperature monitoring) and treatment evaluation.

Study burden and risks

After giving informed consent, patients will undergo a contrast-enhanced pre-treatment MRI on the MR-HIFU system (first visit). This MRI will be used to perform computer simulations of the actual HIFU treatment, thereby assessing the feasibility of the treatment. If the simulations indicate that treatment is feasible, the MR-HIFU procedure will be performed during the second visit. Blood samples will be obtained before and after the MR-HIFU procedure and before surgical resection of the tumor to monitor liver function tests (LFTs) and for future tests. After the MR-HIFU procedure, the patients will stay for observation in the hospital for up to one night. Approximately one to four weeks after the MR-HIFU treatment, the patient will undergo surgical resection of the metastatic liver tumor (standard clinical care). The coagulated tumor volume in the resection specimen will be compared to the MR imaging data obtained during the MR-HIFU treatment. Patients will undergo post-operative follow-up according to standard clinical practice. Patients will be asked about their experiences and the existence of adverse events in two phone calls, which take place one week and 30 days after the MR-HIFU procedure. The most important risks associated with participation in this study include: thermal damage to the skin or subcutaneous muscle (small risk), damage to other abdominal organs (very small risk) and complications associated with anesthesia or MRI contrast agents (very small risk).

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- At least 18 years old;
- Able to give informed consent;
- One or more metastatic liver tumor(s);
- Target tumor is eligible for surgical resection;
- Sufficient physical condition to undergo general anesthesia or deep sedation;
- Waist circumference that allows positioning on the HIFU table-top inside the MR bore;
- Based on a clinically available CT/MRI scan, the liver tumor is potentially accessible for MR-HIFU treatment (this relies on the judgment of the investigator and physicians).

Exclusion criteria

- Contra-indication for MRI scanning according to the hospital guidelines;
- Contra-indication to injection of gadolinium-based contrast agent, including known prior allergic reaction to any contrast-agent, and renal failure (defined as GFR < 30mL/min/1.73m2);
- Patients who prefer not to be informed about unexpected MRI findings;
- Surgical clips or considerable scar tissue in the HIFU beam path;
- Past or future other loco regional therapies for the same tumor (that is to be treated with MR-HIFU ablation) until the moment of surgical resection, such as (but not restricted to) RF ablation, microwave ablation, cryoablation, chemo-embolization, radio-embolization, or radiotherapy.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	High intensity focused ultrasound ablation
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	12-03-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-08-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-04-2015
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: 25843
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45332.041.13
OMON	NL-OMON25843