MRI-guided focused ultrasound (MR-HIFU) treatment of liver tumors

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25843

Source
Nationaal Trial Register

Brief title
MALTA

Health condition

Metastatic liver tumors
Levermetastasen

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Center for Translational Molecular Medicine (www.ctmm.nl), project VOLTA (grant 05T-201).

Intervention

Outcome measures

Primary outcome

Correspondance of the ablated volumes on MR thermometry (obtained per-procedural), MR imaging (obtained post-procedural), and histopathology (obtained from resection specimen)

Secondary outcome

Safety (adverse events, liver function tests)

Study description

Background summary

MR-HIFU allows for completely non-invasive tumor ablation (desctruction with heat) under real-time imaging and temperature guidance. In this treat-and-resect study, patients with a liver metastasis will first receive an MRI scan. This allows the researchers to determine if the MR-HIFU treatment is possible. If so, the patient will be treated with MR-HIFU before undergoing standard surgical removal of the tumor. Blood samples will be obtained to study the biochemical effect on the liver. The resected tumor will be analyzed to study the effect of the MR-HIFU treatment on the tumor.

Study objective

Accurate MR-HIFU ablation of liver metastases is feasible

Study design

Timepoint 1: pre-treatment MRI
Timepoint 2: MR-HIFU procedure

Note: surgical resection of the targeted tumor (standard clinical care) will follow 1-4 weeks after the MR-HIFU procedure. The resection specimen will be used for comparison with the MR thermometry and imaging data.

Intervention

(partial) Magnetic Resonance-guided High Intensity Focused Ultrasound ablation of one liver metastasis

Contacts

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Eligibility criteria

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

Exclusion criteria

- Contra-indication for MRI scanning
- 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
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-03-2014
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-02-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41228
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4324
NTR-old	NTR4473
CCMO	NL45332.041.13
OMON	NL-OMON41228

Study results

Summary results

For an introduction, please refer to: Wijlemans JW, Bartels LW, Deckers R, Ries M, Mali WP, Moonen CT, Van den Bosch MA. Magnetic resonance-guided high-intensity focused ultrasound (MR-HIFU) ablation of liver tumours. Cancer Imaging. 2012 Sep 28;12:387-94.