

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

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Accurate MR-HIFU ablation of liver metastases is feasible

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25843

Bron

NTR

Verkorte titel

MALTA

Aandoening

Metastatic liver tumors
Levermetastasen

Ondersteuning

Primaire sponsor: University Medical Center Utrecht

Overige ondersteuning: Center for Translational Molecular Medicine (www.ctmm.nl), project VOLTA (grant 05T-201).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

MR-HIFU allows for completely non-invasive tumor ablation (destruction 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.

Doel van het onderzoek

Accurate MR-HIFU ablation of liver metastases is feasible

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 $GFR < 30 \text{ mL/min/1.73m}^2$)
- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	13-02-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41228
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.