Magnetic Resonance imaging-guided high intensity focused ultrasound for patients with Desmoid-type fibromatosis

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Patients with desmoid-type fibromatosis could benefit from treatment with MR-HIFU.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23077

Bron
Nationaal Trial Register

Verkorte titel
MAGNIFIED trial

Aandoening

Desmoid-type fibromatosis

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: Desmoid Tumor Research Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Analysis of efficacy:
MR-HIFU will be considered as an effective treatment modality for DTF patients if a success is

observed in >3 of the 13 patients. If a success is observed in ≤3 of the 13 DTF patients, it is concluded that MR-HIFU is not an effective treatment strategy in these patients, and should not be further investigated. Otherwise, this study will conclude that this treatment strategy is effective and sufficiently promising, and warrants further investigation in this patient population. The primary outcome will be presented in absolute numbers and proportions.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Desmoid-type fibromatosis (DTF) is a rare, histologically benign soft tissue tumor. Although incapable of metastasizing, the clinical course is unpredictable and can be aggressive because of local invasive growth. Many intensive treatments (i.e. surgery, systemic treatments, radiotherapy) may be considered in patients with symptomatic disease but unfortunately, these 'traditional' treatment options do not guarantee success. Local recurrence after surgery remains high and the response rates after systemic treatment and radiotherapy are disappointing. Active surveillance is now recommended as a first line management for most patients with DTF. However, symptoms can be severe, and patients are often limited in their daily life because of pain, functional deficits, and/or psychological problems. Therefore, development of new treatment modalities which improve quality of life and/or achieve tumor control, while minimizing any possible harm, are warranted. MR-HIFU is a promising non-invasive technique that uses focused ultrasound waves to thermally ablate tumors, while minimizing side effects to surrounding healthy tissues. Given the promising outcomes of previous studies of MR-HIFU as treatment modality for DTF patients, we hypothesize that DTF patients could benefit from treatment with MR-HIFU.

Objective: The aim of this study is to assess the efficacy of MR-HIFU as a treatment modality for desmoid-type fibromatosis (DTF).

Study design: This is a two-stage, open-label, single-arm, phase 2 prospective study.

Study population: All adult patients with DTF with failure of active surveillance (due to tumor growth and/or new or worsening symptoms) for their current desmoid tumor are considered eligible for the study.

Intervention (if applicable): All patients will undergo an adequate MR-HIFU treatment procedure with the aim of total tumor ablation (consisting of a single or multiple treatments).

Main study parameters/endpoints: Primary outcome of the trial will be the patient satisfaction rate 12 months after the completion of the MR-HIFU procedure(s). Patient satisfaction is being defined as the number of patients achieving their own personal satisfaction score. Secondary outcomes include the presence of non-perfused volume on MRI after the MR-HIFU procedure, change in tumor volume, the response rate according to the Response Evaluation Criteria in Solid Tumors version 1.1. (RECIST v.1.1) and mRECIST criteria, the number of patients who need a re-intervention, time to (re)growth, duration of tumor response, and

patient satisfaction, adverse events, change in symptoms, pain scores, and health-related quality of life (HRQoL) in the first 12 months after treatment.

Doel van het onderzoek

Patients with desmoid-type fibromatosis could benefit from treatment with MR-HIFU.

Onderzoeksopzet

An interim analysis will be done after the first 8 patients have been in follow-up for 12 months after completion of MR-HIFU treatment (phase 1). If response is observed in >1 patients, another 5 patients will be included and treated with MR-HIFU (phase 2).

With regard to the timepoints of the primary and secondary outcomes, we refer to the section 'primary and secondary outcomes'.

Onderzoeksproduct en/of interventie

MR-HIFU treatment

Contactpersonen

Publiek

University Medical Center Utrecht
Anne-Rose Schut

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Wetenschappelijk

University Medical Center Utrecht
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- Patients > 18 years
- Histological evidence of DTF
- Patients with failure of active surveillance* for their present manifestation of DTF
- Desmoid tumor must be targetable with MR-HIFU device
- Desmoid tumor must be visible on pre-treatment MR-imaging
- Patient is able to fit in the MRI gantry
- Capable to understand and sign informed consent

*failure of active surveillance due to tumor growth and/or new or worsening symptoms

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Personal or family history of familial adenomatous polyposis (FAP)
- Intra-abdominal tumor localization
- Patients with a tumor greater than 10 centimeters
- Patients who have undergone prior active treatment (systemic therapy, radiotherapy, prior ablation) for the present manifestation of DTF
- Patients with recurrent disease within 12 months after treatment for their prior desmoid tumor
- Patients weighing more than 140 kilograms
- Pregnancy
- Contra indications to MRI, MRI contrast agents or sedation
- Unavoidable critical structures or dense tissues in target area*
- Any other condition, which in the opinion of the investigators, would put the patient at increased risk or otherwise make the patients unsuitable for this study

*as judged by the operator. e.g.: nerve bundles, skin, extensive scarring, non-targeted bones, air (e.g. hollow viscera), (external) fixation device, surgical clips

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	13
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54042
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9679
CCMO	NL76201.041.21
OMON	NL-OMON54042

Resultaten