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

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

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON54042

Source
ToetsingOnline

Brief title
MAGNIFIED trial

Condition

- Soft tissue neoplasms malignant and unspecified
- Soft tissue therapeutic procedures

Synonym
aggressive fibromatosis, Desmoid tumour

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: The Desmoid Tumor Research Foundation

Intervention

Keyword: Desmoid-type fibromatosis, minimally invasive, MR-HIFU, treatment

Outcome measures

Primary outcome

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 outcome

Secondary outcomes include the presence of non-perfused volume on MRI after the MR-HIFU procedure, change in tumour 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 tumour 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.

Study description

Background summary

Desmoid-type fibromatosis (DTF) is a rare, histologically benign soft tissue tumour. 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 tumour control, while minimising any possible harm, are warranted. MR-HIFU is a promising non-invasive technique that uses focused ultrasound waves to thermally ablate tumours, 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.

Study 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.

Intervention

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

Study burden and risks

Participation in the study will bring limited to moderate burden and risks to the patient. In terms of benefits, patients participating in this study may improve their personal satisfaction score and/or may experience durable control or reduction of tumour volume as a result of the MR-HIFU intervention. Patients treated with MR-HIFU are at (small) risk for skin burn, thermal damage to adjacent structures, and pain caused by the MR-HIFU procedure. The eligibility criteria will minimize the risk of damage of critical structures. Serious adverse events due to the intervention are not to be expected. In terms of burden, patients will need to pay a visit or visits to the University Medical Center Utrecht (UMCU) for one pre-treatment out-patient clinic visit and the MR-HIFU treatment procedure itself and they will be required to undergo an intervention under sedation (maximum duration of 4 hours). The follow-up schedule of this study states the same number of visits as the current consensus-based guideline for desmoid tumours. Patients will be asked to fill in the HRQoL questionnaires before and 6 and 12 months after completion of treatment. Altogether, we consider the burden and risks to be limited to moderate

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients > 16 years
- Histological evidence of DTF
- Patients with failure of active surveillance* for their present manifestation of DTF
- Desmoid tumour must be targetable with MR-HIFU device
- Desmoid tumour 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

Exclusion criteria

- Personal or family history of familial adenomatous polyposis (FAP)
- Intra-abdominal tumour localization
- Patients with a tumour greater than 12 centimetres (as measured on intake MRI by a radiologist).If the tumor is larger than 10 cm in one dimension, the other two dimensions of the tumor must not be greater than half of the largest dimension (i.e. if the largest dimension is 12 cm, the other dimensions mustn*t be larger than 6 cm).
- Patients who haveundergone prior systemic therapy or radiotherapy for the present manifestation of DTF
- 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*
- Inability to tolerate stationary position for the duration of the procedure
- 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, implants, or prothesis

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-02-2022
Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	Sonalleve MR-HIFU system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-12-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-03-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	31-05-2024
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: 23077
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL76201.041.21
Other	NTR NL9679