MRI-guided High-Intensity Focused Ultrasound Ablation of Breast Cancer.

No registrations found.

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

Summary

ID

NL-OMON25994

Source
NTR

Health condition

Breast cancer, MRI-guided High-Intensity Focused Ultrasound Ablation

Sponsors and support

Primary sponsor: University Medical Center Utrecht, Department of Radiology
Source(s) of monetary or material Support: Center for Translational Molecular Medicine (CTMM)

Intervention

Outcome measures

Primary outcome

The main objective of this feasibility study is to determine treatment accuracy of MR-HIFU in breast cancer patients using a dedicated MR-HIFU breast system.

Secondary outcome

The secondary objective of this feasibility study is to determine safety of MR-HIFU in breast cancer patients using a dedicated MR-HIFU breast system.

Study description

Background summary

N/A

Study objective

N/A

Study design

MRI scan and HIFU treatment.

Intervention

Intervention with MR-HIFU:

HIFU uses focused ultrasound waves to heat and thermally ablate tissue. In this study only a part of the breast tumor will be ablated. The MRI system identifies the ultrasound path and monitors heat rise in the breast tissue and the surrounding structures.

Contacts

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Eligibility criteria

Inclusion criteria

1. Female aged 18 years and over;

2. Able to give informed consent herself;

3. World Health Organization performance score ≤ 2;

4. Weight < 80 kg;

5. The target breast fits into the cup of the dedicated MR-HIFU breast system;

6. Patients with cT1-2 (≥1.0 cm) invasive breast cancer, confirmed by histopathology;

7. Size of the tumor is determined on mammography or ultrasound.

Exclusion criteria

1. Patients treated with neo-adjuvant systemic therapy;

2. Contra-indications for MRI scanning according to the hospital guidelines;

3. Contra-indications to injection of gadolinium-based contrast agent, including known prior allergic reaction to any contrast-agent, and renal failure, defined by GFR < 30mL/min/1.73m2;

4. Macro calcifications around the targeted tumor;

5. Scar tissue or surgical clips in the direct path of the HIFU beam;

6. Pregnant or lactating women;

7. Patients who don't want to be informed about unexpected findings on MRI.

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:	Recruiting
Start date (anticipated):	13-09-2012
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-09-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39336
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3472

Register	ID
NTR-old	NTR3624
CCMO	NL39519.041.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39336

Study results

Summary results
N/A