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
Nationaal Trial Register

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

Public
Department of Radiology
University Medical Center Utrecht
Heidelberglaan 100
Laura Merckel
Utrecht 3584 CX
The Netherlands
+31 (0)88 7550286
Scientific
Department of Radiology
University Medical Center Utrecht
Heidelberglaan 100
Laura Merckel
Utrecht 3584 CX
The Netherlands
+31 (0)88 7550286

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