Clinical target volumes in breast-conserving therapy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24243

Source
NTR

Health condition

Target volume delineation in radiotherapy.

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

Clinical target volumes pre-BCS and post-BCS on both CT and MR imaging.

Secondary outcome

N/A

Study description

Background summary

Standard breast-conserving therapy consists of breast-conserving surgery (BCS) followed by radiotherapy. Previous planning studies on pre-operative imaging and target volume delineation have observed a theoretical reduction in irradiated volumes and a reduction in radiation dose in organs at risk, compared to post-operative imaging. Smaller irradiated volumes might result in decreased toxicity and improved cosmetic outcome. Furthermore, due to improved soft tissue contrast, studies have shown the possible advantages of MR imaging instead of CT imaging in the post-operative setting. In this study we will compare both pre- vs. post-operative target volume delineation, and CT vs. MR imaging.

Study objective

Pre-operative target volume delineation instead of post-operative delineation and the use of MRI instead of CT, would lead to improved target volume delineation.

Study design

1. Pre-operative;

2. Post-operative (2x)

Intervention

1. Pre-operative CE-CT+CE-MRI;

2. Post-operative CE-CT+CE-MRI. (x2).

Contacts

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Eligibility criteria

Inclusion criteria

1. Female gender;

2. Age ¡Ý 18 years, ¡Ü 70 years;

3. cTis-T2N0Mx breast cancer;

4. Scheduled for breast-conserving therapy;

5. Before breast-conserving surgery;

6. Written informed consent.

Exclusion criteria

1. Legal incapability;

2. Insufficient command of the Dutch language;

3. History of ipsilateral breast surgery (benign, malign, augmentation, reduction);

4. Inability to maintain the standard supine RT treatment position for 30 minutes;

5. Exclusion criteria for MRI following the protocol of the department of radiology UMCU;

6. Severe renal failure of creatinine clearance of <50mL/min/1.73m2;

7. Idodine allergy (contraindication for iodine-based intravenous contrast agents);

8. Treated with neo-adjuvant chemotherapy;

9. Treated with modified radical mastectomy;

10. Treated with axillary lymph node dissection.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2011
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date:	16-12-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38406
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3050
NTR-old	NTR3198
CCMO	NL37045.041.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38406

Study results

Summary results
N/A