Clinical target volumes in breast-conserving therapy.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24243

Bron
NTR

Aandoening

Target volume delineation in radiotherapy.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: University Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Pre-operative;

2. Post-operative (2x)

Onderzoeksproduct en/of interventie

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

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

Contactpersonen

Publiek

Universitair Medisch Centrum
Radiotherapie, HP Q00.118
Postbus 85500
M.D. Hartogh, den
Utrecht 3508 GA
The Netherlands
+31 (0)88 7550474

Wetenschappelijk

Universitair Medisch Centrum
Radiotherapie, HP Q00.118
Postbus 85500
M.D. Hartogh, den
Utrecht 3508 GA
The Netherlands
+31 (0)88 7550474

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-11-2011
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	16-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38406
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A