Pre-operative CT scan in breast conserving therapy for more accurate radiation boost volume delineation.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON35059

Source
ToetsingOnline

Brief title
PRESCRIBE

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breastcancer, cancer of the breast

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: boost, breastcancer, irradiation, pre-operative CT scan

Outcome measures

Primary outcome

Primary: Difference in position of the pre-operative tumour on CT and

postoperative reconstruction of the tumour-location using current standard

information: *GTVsim* en GTVpre

Difference in position of the radiotherapy boost by using the pre- operative CT

scan, compared with the postoperative simulation CT scan: CTVsim en CTVpre

Difference in volume of CTVsim en CTVpre

Secondary outcome

Secondary: Change of contour of the breast after surgery

Decreasing the interobserver delineation on CTVpre compared to CTVsim between

the 4 observers

Study description

Background summary

In the Netherlands, yearly about 12000 women are diagnosed with invasive breast cancer. Of these, almost 1300 women are diagnosed with carcinoma in situ (Dutch Cancer registration, NKR). The lifetime chance for women developing breast cancer is 12-13%. Treatment for breast cancer patients is a rapidly changing field. In 2002 the first Dutch multidisciplinairy guideline for breast cancer treatment appeared. The treatment guideline was renewed in 2005 and 2008.

(breast cancer guideline 2005 and 2008)
Since the 90*s the majority of women with breast cancer are treated with breast conserving therapy. Several randomised trials show no difference in survival between breast conserving therapy and modified radical mastectomy for early breast cancer (stage T1-2). (Jacobson et al, 1995; Fisher et al,1995; Sarrazin et al, 1989; van Dongen et al, 2000; Veronesi et al, 1995).
Radiotherapy as part of breast conserving treatment consists of radiation of the whole breast and a boost dose to the tumour excision area. This boost dose can be given as a simultaneous integrated boost or sequentially after radiation of the whole breast. Results of the boost versus no boost trial show, after 10 years follow up a 50% decrease of local failure in favour of the group treated with a boost. (Bartelink et al, 2007). This is independent of the systemic adjuvant given therapy.

Combining different imaging modalities (Magnetic Resonance Imaging (MRI), Computed Tomography (CT), ultrasound and mammography) can give reliable information on the place and extension to the tumour. This imaging serves as a guide for the surgical excision; moreover, preoperative imaging is used for defining the radiotherapy boost volume more precisely. During the operation the surgeon places one or more clips in the excisional cavity. These clips are mostly situated at the deepest point of the excision cavity, but also clips spread around the excision cavity are seen. Defining the boost volume is done by using pre-operative palpation of the tumour, pre-operative imaging, the operatively placed clips and the postoperative CT scan.
Despite of all this information, in practice a great uncertainty of the position of the original tumour exists, leading to interobserver variety in delineation of the target volume. In a trial with five observers and 18 patients a conformity index of 0.56 was found (range 0.37-0.74). This indicates that among the participants there was agreement on only slightly more than half of the delineated volume. (Struikmans et al, 2005). In light of these uncertainties a relative large uncertainty margin is taken for the definitive boost irradiation.

Currently, a postoperative simulation CT scan is used for a dose calculation of the radiotherapy boost. This gives more accurate (3D) information on dose homogeneity and dose to critical organs (lung, heart and contralateral breast) than dose calculations using conventional simulation (under fluoroscopy images). However, several studies have shown that using a CT-based planning can result in 1.29 to 1.6 times larger volumes than the conventional boost simulation calculations. (Hanbeukers et al, 2009, van der Laan et al, 2008).

The boost versus no boost trial shows that in the no boost group 86% of patients had an excellent or good global cosmetic outcome. In the boost group this was significantly less with 71% (Vrieling et al, 1999). Besides the boost other significant factors influencing cosmesis are a caudal localisation of the tumour, a larger excision volume and postoperative complications (Vrieling et al, 2000). Previous studies have shown that radiation volume and radiation dose

are also factors which significantly effect the cosmetic outcome. (van Limbergen et al, 1989; Borger et al, 1994).

Dynamic contrast enhanced CT scan of the breast seems to be effective for detecting intraductal extension of breast cancer. A pre-operative CT scan has also shown to be useful for pre-operative assessment for suitability of breast conserving treatment (Yamamoto et al, 2006). The tumour is visible on CT as a dense lesion and shows early contrast enhancement as seen in dynamic MRI. CT is less sensitive than a mammography for detecting microcalcifications, if this is the only sign of early breast cancer (Ternier et al, 2006).

The location of the original tumour is difficult to define on a postoperative CT scan. When a pre-operative CT scan in radiotherapy position is performed, the tumour may serve as a base for determination of the boost area on the postoperative scan, (Clinical Target Volume (CTV), when the pre-operative scan is matched with the postoperative scan. Possibly the CTV can be defined more accurately which could lead to a decrease of the boost volume.
Possible contour change of the breast due to surgery should be taken in consideration.

Study objective

The purpose of this study is to investigate whether the pre-operative contrast enhanced CT scan can be used for determination of the pre-operative tumour localisation, with the aim of increasing the accuracy of the boost area. If so, the boost volume might possibly be decreased. The usefulness of the pre-operative CT scan for this aim partly depends on the question in what percentage of patients the tumour is clearly visible on this scan and of the possibility of matching the pre-operative CT scan with the simulation CT scan. In other words, does the lumpectomy cause a contour change of the breast, which makes the pre-operative CT scan unusable.

Study design

All women with stage T1-3, N0-2 breast cancer, pre-operatively seen in the radiotherapy department, can be asked to join this study. After written informed consent, patients will have a pre-operative CT scan in radiation position after intravenous contrast has been given. The simulation CT scan will preferably made 3-4 weeks after surgery, without contrast.

Intervention

Pre operative CT scan will be performed with the following conditions:
* CT scan (GE, The LightSpeed® RT16)
* 2.5 mm slides
* Radiotherapy position, indicating supine on a C-Qual breast board (CIVCO

medical solutions)
* Iv contrast (Otiray® 350, Mallinckrodt Medical B.V.) 90 ml
* Isocenter marking by using a lead coil and a tattoo point
* Marking the breast glandular tissue by electra wire

Study burden and risks

There will be a minimal additional X-ray exposure, which is negligible compared to the radiation exposure due to radiotherapy. There is also a minimal risk of side effects of the intravenous contrast.

Stopping rule
If it appears that after 5 scanned patients, on 3 or more patients the tumour is not visible on the pre-operative CT scan, the study will be discontinued.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

cT1-3N0 breastcancer, calculated creatinine clearance > 60 ml/liter (Cockroft) , informed consent

Exclusion criteria

post operative mastitis or wounddefect, contra indication for iv.contrast, neo adjuvant systemic treatment

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-06-2010
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Optiray 350
Registration:	Yes - CE intended use

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL31424.018.10