Pre-operative CT to improve delineation of the tumorbed in radiotherapy for breast cancer.

Published: 07-07-2008
Last updated: 11-05-2024

The aim of this study is to investigate the effect of incorporating a CT-thorax in the target volume delineation process on 1) percentage of the target volume that receives less than 85% of the prescribed dose, 2) the size of the irradiated boost...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON33679

Source
ToetsingOnline

Brief title
Delineation of the tumorbed in breast cancer.

Condition

- Miscellaneous and site unspecified neoplasms benign
- Breast therapeutic procedures

Synonym
Breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO clinic
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast cancer, Delineation of target volume, Pre-operative CT-scan, Radiation therapy

Outcome measures

Primary outcome

1) The percentage of the PTV-2 receiving < 85% of the dose, if treated with

the RT-plan for PTV-1.

2) The volume receiving > 95% of the prescribed dose.

Secondary outcome

Other endpoints will be interobserver variation, as measured by

1) percent volume overlap of the PTVs;

2) difference in standard deviation of the average PTV-1 and PTV-2;

3) center of mass assay.

Study description

Background summary

Whole breast irradiation with 50 Gy after lumpectomy for breast cancer has been shown to reduce the local recurrence rate with a factor 3 to 4. An additional boost of 16 Gy to the tumorbed has been shown to improve the local control rate even further with a factor 2. However, this boost dose appears to reduce not only the local recurrences in the tumorbed, but also elsewhere in the breast, suggesting that the boost may not always be delivered at the correct region. In addition, even with the boost dose of 16 Gy, the local recurrence rate in young patients < 40 yr is still quite high - with the majority of recurrences in the tumorbed. Consequently, further improvement of the local control, especially in young women, is still an important aim to pursue, in order to maintain breast conserving therapy (BCT) as an acceptable treatment option in young women. One way to improve local control may be to increase the dose [Young Boost Trial], but also to improve the definition of the tumorbed, i.e. the target volume for boost irradiation. We expect that visualization of the tumor priro to surgery on a CT scan made in radiation treatment position will improve the definition

of the target volume for boost irradiation.

Study objective

The aim of this study is to investigate the effect of incorporating a CT-thorax in the target volume delineation process on 1) percentage of the target volume that receives less than 85% of the prescribed dose, 2) the size of the irradiated boost volumes, and 3) the interobserver variation in target volume delineation.

Study design

A CT scan of the thorax will be made < 3 weeks prior to surgery, with the patient in radiation treatment position. After breast conserving surgery, patients will be referred for post-operative radiotherapy according to the standard guidelines. Prior to radiotherapy, a standard CT thorax scan will be made for treatment planning.
The planning target volume (PTV) for the boost will be delineated according to the MAASTRO protocol, by three independent observers (PTV-1A-C), using the planning CT only. Delineation of the boost will be repeated after 3D registration of the pre-operative CT scan with the planning CT-scan (PTV-2A-C). Thereafter, consensus will be obtained for the PTV-1A-C and the PTV-2A-C, resulting in one PTV-1 and one PTV-2 for each patient. Radiation treatment plans (RT-plans) will subsequently be designed for PTV-1 and PTV-2. Coverage of the treatment plans by the 85% isodose for both PTV-1- and PTV-2, and the irradiated volumes (percentage of the volume receiving 95% or more (V95)) will be calculated. Patients will be treated with the treatment plan for PTV-2.

Both a contrast enhanced CT and a CT without contrast will be made to investigate in which patients contrast enhancement has additional value.

Study burden and risks

Patients will only be included after written informed consent. The preoperative CE-CT-thorax-scan yields little additional radiation exposure, which will however be negligible compared to the radiation treatment to be given because of the breast cancer. In addition, there is a small risk on an allergic reaction to the intravenous contrast, and on renal complications. Therefore, renal function will be checked prior to giving contrast. A kreatinine clearance < 60 ml/min will be a contra-indication for contrast. The pre-operative CT-scan will be made in MAASTRO clinic, requiring an additional visit to MAASTRO clinic. A possible benefit may be that the pre-operative CE-CT thorax may improve the definition of the target volume, and thereby 1) reduce the risk on a local recurrence, and 2) reduce the size of the irradiated volume, thereby improving the cosmetic outcome. A possible drawback may be that the size of the

irradiated volume increases, which may detoriate the cosmetic outcome.

Contacts

Public
MAASTRO clinic

dr. Tanslaan 12
6229 ET Maastricht
Nederland
Scientific
MAASTRO clinic

dr. Tanslaan 12
6229 ET Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Female patients with proven breast cancer, to be treated with breast conserving therapy, and a visible mass on mammography or ultrasound > 0.5 cm.

Exclusion criteria

* All contra-indications for breast conserving therapy, i.e. pregnancy, multicentricity, inoperable disease, or a too large tumor in a relatively too small breast.

* All contra-indications for intravenous contrast, i.e. iodine allergy, renal malfunction (kreatinine clearance < 60 ml/min), , previous allergic reaction to i.v. contrast, M. Kahler, use of NSAIDs, Diuretics or Metformine.
* Absence of tumor mass > 0.5 cm on mammography or ultrasound.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2008
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-04-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL22918.068.08