Partial Breast Radiotherapy in Low-risk Breast cancer group using a stereotactic MR-guided adaptive approach; a phase II study

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The main goal of this prospective phase II observational study of APBI for *low risk* breast cancer (cT1-T2N0M0) is to evaluate early and early-delayed toxicity with this approach, after daily adaptive radiotherapy treatment.

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

Summary

ID

NL-OMON45437

Source
ToetsingOnline

Brief title
PARLOB

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, carcinoma of the breast

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MR-guided, partial breast, radiotherapy, stereotactic

Outcome measures

Primary outcome

To evaluate early and early-delayed toxicity (defined as the first year following treatment). Toxicity will be monitored at fixed time points using CTCAE, before and during treatment and 3, 9 and 18 months after breast conserving surgery

Secondary outcome

Cosmetic outcome and Quality of Life are important secondary outcome measures.

Quality of Life will be evaluated using EORTC-QOL questionnaires (EORTC-QoL C30 & Breast Cancer module QLQ BR23).

Cosmetic outcome will be evaluated using three previously used methods in VUmc consisting of a panel, BCCT.core-software and patient self-evaluation.

Offline dosimetric comparison between this new MR-guided adaptive approach in breath-hold and current techniques described in recent literature

Study description

Background summary

Breast conserving therapy (BCT) consists of local excision of the primary tumor followed by postoperative radiotherapy (RT) of the remaining glandular tissue of the ipsilateral breast, with or without surdosage to the surgical cavity. Several recently conducted randomized trials have demonstrated equipoise with respect to local control between this approach and accelerated partial breast irradiation (APBI) [Strnad 2016, Livi 2015]. Livi et al has proven an

hypofractionated scheme to be equally efficient and tolerated as well als conventionally fractionated treatments, with the advantage that treatment can be deliverd within two weeks.

The clinical introduction of stereotactic MRI-guided adaptive radiation therapy (SMART) using the MRIdian treatment machine will enable visualisatoin of target volume and adjacent normal organs such as the heart and lungs prior to and during treatment delivery. Online imaging allows to deliverd "gated" treatment, enabling the use of small uncertainty margins, which can potentially limit clinical toxicity. One further advantage of the SMART approach is the ability to perform adaptive treatment planning for each delivered fraciton. This means that de original treatment plan can be optimized immediately prior to treatment delivery, especially optimized with respect to the position and volume of the adjacent normal organs such as heart and lungs.

Despite the results of Livi et al, partial breast is not yet a standard treatment in the Netherlands for low-risk breast cancer. Because of the relatively short follow-up of published randomised studies, Dutch guidelines recommended partial breast radiotherapy to be investigated within study context [www.oncoline.nl]. The MRIdian allows more accurate partial breast radiation delivery en the results will be evaluated in this phase 2 study.

Study objective

The main goal of this prospective phase II observational study of APBI for *low risk* breast cancer (cT1-T2N0M0) is to evaluate early and early-delayed toxicity with this approach, after daily adaptive radiotherapy treatment.

Study design

A prospective phase II observational study.

Study burden and risks

The use of APBI has a number of potential benefits for patients. Most importantly, irradiation of a smaller breast volume obviously results in lower radiation doses to surrounding normal tissues such as the chest wall, lung, and for left-sided breast cancer the heart, and allows for hypofractionated treatment with a higher dose per fraction. This approach could decrease early, early-delayed and late toxicity, potentially resulting in optimal breast cosmetics. Finally, the use of APBI decreases both the number of radiation fractions as well as the overall treatment duration for patients in comparison to the standard treatment of 3 to 4 weeks.

This novel SMART approach could set a new standard of care for patients with low-risk breast cancer by limiting radiation doses to surrounding normal organs

and thereby potentially decreasing radiation-induced toxicity. Disadvantages for patients include the need to be positioned within the MRI bore during radiation delivery, and a prolonged time per treatment fraction (estimated at 60 minutes per fraction compared to 20 minutes per fraction for standard treatment on the linac), which has to be weighed against the use of a total of only five fractions. As the radiation fractionation scheme that is used in this study has been evaluated in prior trials, no further patient-related risks are anticipated.

Patient will be followed-up with the frequency according to regional guidelines for breast cancer. The extra time for filling in the questionnaires will be around 5-10 minutes

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

- Age > 50 years
- WHO performance score 0-2
- Pathology proven breast cancer with following histology: invasive ductal carcinoma, mucinous, tubular, medullary, colloid cc, and associated LCIS
- Any histologic grade
- Any hormonal receptor status
- T-stage: Tumor size * 3cm (pT1-2)
- N-stage: No positive lymph nodes examined by sentinel lymph node biopsy or axillary lymph node dissection (at least 6 nodes pathologically examined)
- Radical resection of tumor with * 2mm surgical margin free of tumour
- All patients should be able to undergo MRI scans
- Ability to provide written informed consent.
- Ability to perform breath-hold for at least 17 seconds

Exclusion criteria

- Breast cancer histology of invasive lobular carcinoma, ductal carcinoma in situ sec
- Breast cancer with a multicentric or multifocality character
- An extensive intraductal component in pathology examination
- Lympho-vascular invasion in the pathology examination
- Treatment with neoadjuvant chemotherapy before lumpectomy
- Breast conserving surgery with an oncoplastic breast surgery technique
- Re-excision of tumour in ipsilateral breast
- Open surgical wound or wound infection
- Previous irradiation in the ipsilateral breast
- Contra-indications for MRI

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-10-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2017
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	NL58704.029.16