Preoperative Image guided Accelerated Partial Breast Irradiation (PAPBI) in elderly women with early stage Breast cancer; defining radiotherapy sensitivity

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

Summary

ID

NL-OMON32678

Source
ToetsingOnline

Brief title
Preoperative partial breast irradiation: defining RT sensitivity

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer, mammary malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: KWF en NKI-AVL

Intervention

Keyword: breast cancer, genetic profiling, partial breast irradiation, radiotherapy sensitivity

Outcome measures

Primary outcome

mRNA gene expression profiles, miRNA expression profiles and DNA copy number changes associated with response to radiotherapy defined as pathologic response assessed in the lumpectomy 6 weeks after radiotherapy will be identified. 60 Patients will be studied as a test set to identify predictive profiles.

Responders are defined as Complete Respons and >50% Partial Response 6 weeks after radiotherapy. It is estimated, based on literature, that 50% of the patients will be defined responders. 60 Patients will be studied as a test set to identify predictive profiles; 60 patients will be used as a validation set.

Secondary outcome

Cosmetic evaluation will take place including digital photographs which will be analyze using computer software as well as questionnaires for the patient and treating physician.

Quality of life questionnaires.

Study description

Background summary

Patients with early stage breast cancer are treated with a combination of surgery, radiotherapy and often with systemic therapy. Radiotherapy is part of breast conserving therapy and is known to reduce LR rates in all patients with 60-70% although the absolute benefit differs in different subgroups. So far, no patient groups can be defined in whom radiotherapy would not be necessary. It is estimated that in approximately half of the patients whole breast radiotherapy is not necessary, while in others the tumor might be resistant to radiotherapy. It is likely that tumor cells differ in their response to radiotherapy and thus influence the LR rate after BCT. If it would be possible to predict tumor response to radiotherapy, a more tailored treatment can be advised to individual patients (higher boost dose or primary mastectomy).

Study objective

This research project is directed at assessing tumor response to radiotherapy. The goal of the study is to develop a gene expression profile that predicts response to radiotherapy in early breast cancer patients, allowing for optimal treatment strategy. When correlations will be seen, the major advantage of such profiles is to tailor breast cancer treatment. When it is possible to predict which tumors will recur and which tumor are (non-) responsive to radiotherapy, patients can be more accurately advised to breast-conserving therapy.

PBI will be performed with image guided external-beam pre-operatively radiotherapy. We use 3D-IMRT radiotherapy techniques and CT-guided planning that is widely available and used by radiation oncologists in both academic and community settings. If successful, this approach would provide a readily exportable treatment technique.

Study design

120 women>=60 years with cT1-2pN0 breast cancer will be given preoperative PAPBI 10 x 4 Gy (12 days). As the tumor remains *in situ* during irradiation, accurate tumor delineation and control of accurate radiation dose delivery to the tumor becomes possible by treating these patients with a cone beam CT linear accelerator. From biopsies and fine needle aspiration taken of the tumor before, during radiotherapy and at time of operation RNA and DNA will be isolated. mRNA gene expression profiles, miRNA expression profiles and DNA copy number changes associated with response to radiotherapy defined as pathologic response assessed in the lumpectomy 6 weeks after radiotherapy will be identified. 60 Patients will be studied as a test set to identify predictive profiles; 60 patients will be used as a validation set.

Study burden and risks

Local recurrence (LR) after breast-conserving therapy is age related. Patients 60 years of age and older have a low risk for LR. If a LR occurs, this is

mainly at the original tumorbed (80%). This fact, combined with the addition of MRI (detects multifocal disease in 11%) to select patients with unifocoal lesions, holds the LR risk for LR outside the irradiated volume to be very low.

Especially the long treatment period of radiotherapy is aggravating for most people. The radiation scheme in the proposed study is fairly shorter 2 weeks (10x) instead of 6 weeks (30x). Also, the irradiated volume of the breast irradiated is much smaller, which will hold less acute and late toxicity during and after treatment.

The additional procedures in this study are: biopsies before radiotherapy, cytology at day 2 and 12 of radiotherapy, MRI before operation. Also, the sentinel procedure will take place before radiotherapy.

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

Patients >=60 years of age with proven adenocarcinoma of the breast presenting with an unifocal lesion on mammogram and MRI (no diffuse microcalcifications), tumor size 1.0-3.0 cm.

Exclusion criteria

age < 60 year, multifocal disease, lobulair carcinoom, pN+

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL24996.031.08