SINGLE DOSE ABLATIVE PREOPERATIVE RADIATION TREATMENT FOR EARLY-STAGE BREAST CANCER IN ELDERLY PATIENTS

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

Summary

ID

NL-OMON54805

Source
ToetsingOnline

Brief title
ABLATIVE

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Pink Ribbon

Intervention

Keyword: ablative, elderly, preoperative, single dose

Outcome measures

Primary outcome

The main objective is to evaluate the pathologic complete response rates

following single dose ablative partial breast radiotherapy

Secondary outcome

Secondary endpoints:

• Rate of radiological response on MRI.

• Quality of life assessment.

• Acute- and late-toxicity assessment.

• Cosmetic outcome assessment.

• Frailty assessment in study population

• Local -, regional - and distant relapse rates.

• Disease free - and overall survival rates.

Tertiary endpoint:

• Future research on radiotherapy- associated genotyping.

Study description

Background summary

The current treatment for early stage breast cancer consists of
breast-conserving surgery followed by 16-23 radiation fractions on the entire

breast. Despite the good prognosis, the current treatment is perceived as challenging due to the long duration of the radiation treatment. This is particular the case in the elderly patients with co-morbidity. In some cases a mastectomy is performed as a radical alternative for breast-conserving therapy in order to avoid the multiple radiotherapy sessions. Other patients receive inadequate breast cancer treatment when solely endocrine treatment is administered following the diagnosis. Therefore, in elderly patients with early stage breast cancer, optimization of disease management by means of innovative alternatives are required.
An alternative to whole breast irradiation is accelerated partial breast irradiation (APBI) on the previous tumor bed. Given that the great majority of tumor recurrences occur at or near the region of the prior surgery, the latter technique has been investigated to be safe in low-risk breast cancer patients. A great advantage of APBI is the reduction in the number of radiotherapy fractions thereby reducing the treatment duration. In addition, the irradiation of a smaller breast volume could possibly result in decreased toxicity rates and improved breast cosmesis. Intraoperative radiotherapy (IORT) is an APBI method that has the major advantage of administering one fraction immediately after BCS in the operation room. However, external beam APBI trial has the advantage of being non-invasive when compared to single fraction IORT.
The ABLATIVE study evaluates the feasibility of a single dose ablative external beam radiotherapy as an optimal alternative to BCT in elderly patients with early stage and low-risk breast cancer. This approach could result in minimal treatment burden for all patients with low-risk breast cancer, but is of particular interest in selected elderly whom are currently not treated according to guidelines due to comorbidity.

Study objective

The purpose of the study is to investigate the feasibility of a preoperative, single dose, ablative partial breast radiation treatment in patients with early stage breast cancer. This study aims to present a concept that could resolve to some extent the disadvantages of current breast conserving treatment in elderly low-risk breast cancer patients who are currently not treated according to guidelines due to co-morbidity.

Study design

Feasibility study.

Intervention

Preoperative, single dose, ablative partial breast radiotherapy.

Study burden and risks

BURDEN ASSESSMENT
The radiotherapy treatment will take be minimized to a single fraction for the study patient from the conventional 16-23 fractions (3-5 weeks). Despite a reduction in the number of radiotherapy sessions, the burden for the study patient will consist of vigilant clinical and radiological monitoring:
- The sentinel node procedure will be performed in another session than breast conserving surgery in order to assure that no patients with nodal involvement are included.
- 6-7 preoperative MRI scans will be performed for diagnosis, radiotherapy planning and radiological response evaluation. In addition, one MRI will be performed in the first follow-up year following radiotherapy.
- 2 additional FDG-PET-CTs will be performed for radiological response evaluation (optional).
- 3 mammograms will be performed for the monitoring of possible local recurrences.
- the patients will be required to fill in additional questionnaires on quality of life, toxicity, breast cosmesis, frailty and functionality aspects.
- digital photographs of the patient's both breasts will be taken for objective cosmetic response evaluation.

RISK ASSESSMENT
Partial breast irradiation appears to be as effective as whole breast irradiation with regard to local recurrence rates in patients with low-risk breast cancer. Given that strictly this category patients are eligible for the single fraction ablative treatment, we anticipate low local recurrence rates in our study population.
Another risk that is associated with participation is the possibility of increased toxicity in the irradiated area and impaired cosmesis due to a higher radiotherapy fraction dose. Since the ablative radiotherapy dose is strictly intended for (peri)tumoral tissue, thus confined to a limited volume of the breast, we anticipate that the risk on toxicity is low.

BENEFIT AND GROUP RELATEDNESS
By delivering a single fraction ablative radiotherapy dose, we hope to minimize the treatment burden associated with the protracted WBI sessions. Our treatment approach will probably result in less heart, lung or contralateral breast radiotherapy induced toxicity given the reduction in treatment volume.
The concept of a single fraction ablative radiotherapy can be favorable in all early-stage breast cancer patients with low-risk characteristics due to the anticipated reduction in treatment burden. However, elderly patients with low-risk breast cancer that are currently not treated according to guidelines will benefit the most.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

• Females at least 50 years of age, with an unifocal cT1N0M0 non-lobular breast cancer on mammogram/ultrasound/MRI and sentinel node biopsy
• Females at least 70 years of age, with an unifocal cT1-2(maximum 3 cm)N0M0 non-lobular breast cancer on mammogram/ultrasound/MRI and sentinel node biopsy
• Tumor with negative Her2neu receptor and positive estogen receptor
• Adequate communication and understanding skills of the Dutch language

Exclusion criteria

• Legal incapacity
• BRCA gene mutation.
• WHO performance scale > 2.

• Previous history of breast cancer
• Other type of malignancy within 5 years before breast cancer diagnosis.
• Previous history of ipsilateral breast surgery and impaired cosmetic outcome, as assessed by the treating surgeon or radiation-oncologist
• Extensive DCIS component.
• Invasive lobular carcinoma.
• MRI absolute contraindications as defined by the Radiology Department.
• Multicentricity or multifocality on MRI.
• Nodal or other organ involvement with cytological or histological confirmation.
• Treatment with neo-adjuvant chemo- and immunotherapy. .
• Indication adjuvant chemo- and immunotherapy (endocrine treatment is allowed).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-05-2015
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2014
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	22-04-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-02-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-01-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-03-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-07-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-05-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL46017.041.13