Pre- versus Postoperative Accelerated Partial Breast Irradiation in early stage breast cancer patients

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To assess the cosmetic effect of preoperative versus postoperative partial breast irradiation (prePBI vs postPBI)

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

Summary

ID

NL-OMON55435

Source
ToetsingOnline

Brief title
PAPBI-2

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF en de eigen afdeling

Intervention

Keyword: accelerated breast irradiation, breast cancer, partial breast irradiation, radiotherapy

Outcome measures

Primary outcome

Cosmetic outcome at 3 years

Secondary outcome

* Fibrosis/induration

* Breast pain

* Local relapse free survival

* Quality of life

* Disease free survival

* Distant metastases free survival

* Overall survival

Study description

Background summary

Most of the local recurrences (LR) found after breast-conserving therapy are within or close to the tumor bed. (Elkhuizen 1998, Cajucom 1993 Osborne 1992) This pattern of recurrence was confirmed by studies of breast conserving surgery without adjuvant irradiation (Veronesi 1990) and by the update of the NSABP B-06 trial. (Fisher 2002) In the EORTC boost trial, however, 29% of all LR were found outside the area of the original tumor. (Bartelink 2007) Still, a recent review of BCT trials showed that the site of local recurrences after BCT was mostly in the tumor bed, with less than 10% of LR elsewhere in the breast. (Sanders 2007)
This led to the concept of partial breast irradiation. With accelerated partial breast irradiation (APBI), a limited volume of breast tissue is irradiated, allowing for a higher dose per fraction compared to whole breast irradiation (WBI), which is favorable considering the low */* ratio, and thus higher

sensitivity to high dose per fraction.

Study objective

To assess the cosmetic effect of preoperative versus postoperative partial breast irradiation (prePBI vs postPBI)

Study design

Randomized phase III study

Intervention

Preoperative versus postoperative partial accelerated breast irradiation

Study burden and risks

In the previous PAPBI-1 clinical studiy it's proven there's no slight increased risk of postoperative complications). When a postoperative hemorrhage occurs a small operation will be done.

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

* Female patients * 51 years
* cT1-2 (* 3 cm)
* cN0
* Grade I or grade II (biopsy)
* Histologically proven invasive ductal adenocarcinoma
* Unifocal lesions on mammogram and MRI (small satellite lesions adjacent to the tumor are accepted as long as it is suitable for local excision to be determined by the participating centre)
* WHO performance * 2
* Life expectancy * 5 years
* Written informed consent

Exclusion criteria

* Distant metastases
* Lobular invasive carcinomas
* Pure DCIS without invasive tumor
* Grade III in biopsy
* Triple negative tumors
* HER2neu positive tumors
* Lymphvascular invasion in biopsy
* cN1-3
* pN+ (Micro- or macrometastases
* Multicentric / multifocal disease on mammogram or MRI
* Diffuse calcifications on mammogram (Birads 3, 4 or 5)
* Prior treatment for the protocol tumor (no surgery, no neoadjuvant chemotherapy or neoadjuvant hormonal therapy, no previous radiotherapy)
* Previous contralateral breast cancer:
* Other neoplasms in the last 5 years with the exception of:
- Basal cell carcinoma of the skin
- Adequately treated carcinoma in situ of the cervix
* Planned oncoplastic resection with tissue displacement
* No social security affiliation/health insurance
* Participation in another clinical trial that interferes with the locoregional treatment of this protocol

* It is expected that dosimetric constraints cannot be met, ie, lung/heart constraints (see 6.1.5), or if the ratio PTV/ ipsilateral breast >30%

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	01-07-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-03-2018

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-10-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-11-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-05-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
ClinicalTrials.gov	NCT02913729
CCMO	NL53862.031.15