Geometric accuracy of accelerated partial breast irradiation on the Cyberknife using standard surgical clips as a fiducial marker

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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-OMON48772

Source
ToetsingOnline

Brief title
CK-APBI

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
breast cancer, breast carcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: accelerated partial breast irradiation, Cyberknife, geometric accuracy

Outcome measures

Primary outcome

The main study endpoint is to report the geometric uncertainty of CK-APBI in order to calculate the required PTV margin.

Secondary outcome

A first secondary endpoint will report the proportion of patients where the surgical clips, interstitial gold markers and superficial gold markers were successfully used for treatment delivery at each treatment session.

Another secondary endpoint will quality the dosimetric gain of PTV margin reduction using the novel PTV margin compared to a standard expansion of 5 mm.

More particularly the following metric will be evaluated:

o Coverage of the CTV evaluating the V100 and V95, or proportion of the PTV that is receiving 100% or 95% of the prescribed dose

o The mean dose to the ipsilateral breast tissue

o The mean lung dose

o The mean heart dose

The third secondary endpoint will include the acute skin toxicity of CK-APBI using the NCI CTCAE 5 scale. Each breast related symptom of the scale, including oedema, erythema, pain and desquamation will be captured

independently to enable future recalculation and quality assurance of the total

score.

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Study description

Background summary

Over the last decades, the prognosis of breast cancer patients has dramatically improved. Recent SEER data shows a 5-year cancer specific survival for localized breast cancer patients of 98.9%. For this reason, decreasing the burden of treatment has gained attention.
Radiobiological data showed that it is favorable to hypofractionate breast cancer radiotherapy. Most local recurrences of early stage breast cancer occur in the vicinity of the original tumor. This means that it is sufficient to treat only the region of the tumor bed instead of the whole breast. Combining these two strategies results in accelerated partial breast irradiation (APBI). Several multicenter randomized trials showed non-inferior local control of APBI compared to whole breast irradiation. There are several techniques available to deliver APBI. The Cyberknife has the advantages that it is not invasive, can create a highly conformal dose distribution and can track the target real-time during treatment delivery. Therefore, the safety margin needed to compensate for geometric uncertainties during treatment delivery is smaller than with conventional linacs. The exact value of the optimal safety margin is unknown. The aim of our study is to fully assess the geographical uncertainties during CK-APBI, and to calculate the optimal PTV margin required. We will investigate whether we can use the surgical clips instead of implanted interstitial gold markers as fiducials to track the target. These clips are inserted during lumpectomy as a standard procedure to aid the delineation of the tumor bed. These clips are hence per definition within the delineated target volume. Another advantage of using the surgical clips as fiducials instead of interstitial gold markers is that a separate invasive procedure to implant the fiducials would not be necessary. The third type of fiducial that we will test is a gold marker taped onto the breast surface.
After the calculation of the optimal PTV margin, treatment plans will be generated using the new margin, and dose to organs at risk will be compared with the plans using the conventional margin.

Study objective

The primary objective is to prospectively quantify the geometric uncertainty of CK-APBI and to propose a validated PTV margin.

Secondary objectives are:
- To evaluate the success rate of using surgical clips as fiducial markers
- To evaluate the success rate of using a gold marker taped on the breast surface as fiducial marker
- To evaluate the success rate of using implanted interstitial gold markers as fiducial marker
- To calculate the dosimetric gain of PTV margin reduction
- To report acute toxicity and pain of CK-APBI

Study design

The proposed study is a single center cohort study. APBI is an accepted treatment outside clinical trials for highly selected, low-risk breast cancer patients, according to international guidelines [12-16]. Our aim is to improve APBI delivered on the Cyberknife stereotactic system. We will treat a cohort of patients with CK-APBI, using conventional large safety margins. To assess the geometric accuracy, CT scans will be made before each fraction in treatment position. We will test the surgical clips, superficial gold markers an implanted interstitial gold markers as fiducials to track the target.
Every year, about 240 patients are referred to our radiotherapy department that are eligible for APBI. About a third have large titanium or tantalum clips implanted in the tumor bed, so we plan to complete accrual within one year.

Study burden and risks

The risks of this study are estimated to be very small. APBI is an accepted treatment for early stage low-risk breast cancer patients. The inclusion criteria of this study are in accordance to the international guidelines for selection of appropriate candidates for APBI outside clinical trials (see chapter 4).
During the study, a CT scan will be acquired before each treatment fraction. As there are 5 fractions, a total of 5 extra CT scans will be made. Radiation dose of a CT-scan of the breast is estimated to be around 5mSv. This is equivalent to the background yearly radiation dose. Compared to the dose due to the radiation (30,000 mSv), the extra radiation dose by five CT-scans is negligible. It takes about 10 minutes of extra time to acquire the pretreatment CT scan. There are no extra hospital visits.
In normal practice, a new planning CT scan is made in case of anatomical changes or treatment delivery problems. In this study, we will be able to use the daily pretreatment CT scan for this purpose and avoid the extra delay in treatment delivery until the new planning CT scan is performed.
There is no direct benefit of study participation for the patient and the treatment will be accessible for patient not willing to participate to the study.

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
- Age * 50 years
- Stage pTis, pT1 or pT2 (tumor size < 3 cm) breast cancer
- Invasive ductal, mucinous, tubular, medullary or colloid carcinoma or DCIS
- Treated with breast-conserving surgery
- Resection margins negative at ink for invasive cancer and by * 2mm for DCIS
- ER positive
- pN0 confirmed by sentinel node biopsy or axillary lymph node dissection. If the risk of regional metastasis is deemed so low that a sentinel node is not indicated (for example in DCIS), cN0 is sufficient and patients are eligible for trial participation without sentinel node biopsy.
- At least 3 surgical clips in the tumor bed, being large titanium (1 cm) or tantalum type

Exclusion criteria

- Lympho-vascular infiltration
- Extensive intraductal component
- Multifocal or multicentric disease
- Invasive lobular carcinoma
- Distant metastasis
- Neoadjuvant chemotherapy
- Prior irradiation to the chest
- Inability to read Dutch

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):	09-11-2018
Enrollment:	51
Type:	Actual

Ethics review

Approved WMO Date:	14-03-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2019

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL64643.078.18
Other	NTR28413