MRI-guided single dose preoperative radiotherapy in low-risk breast cancer

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON46628

Source
ToetsingOnline

Brief title
ABLATIVE-2

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer, mammary neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast cancer, Preoperative, Radiotherapy, Single dose

Outcome measures

Primary outcome

Pathologic complete response.

Secondary outcome

Radiologic response, relation between radiologic response and pathologic response, relation between pathology of biopsy and surgical specimen, toxicity, relation between immunoresponse and pathologic response, relation between circulation tumor DNA and pathologic response, cosmetic result, quality of life, workability or frailty (depending on age), disease free survival, overall survival.

Study description

Background summary

Patients with early stage breast cancer, with a low risk of recurrence of disease after treatment, are currently being treated with breast-conserving surgery followed by whole or partial breast irradiation according to guidelines. If patients receive partial breast radiotherapy preoperative instead of postoperative, smaller volumes of the breast can be irradiated. Consequently the radiotherapy can be administered in less fractions, even in a single dose. Furthermore, in preoperative partial breast irradiation, tumor response can be monitored and pathologic complete response to radiotherapy can be observed. In an earlier similar trial (ABLATIVE NL46017.041.13) no or only mild toxicity was found after single dose preoperative radiotherapy. In this study a pathologic complete response was observed in 1 out of every 3 treated patients. In the current study we want to investigate whether a predictors for pathologic complete response are present. We will make use of 3T MRI, 7T MRI, a biopsy of the irradiated tumor and liquid biopsies for this cause. If a large proportion of patients achieve a pathologic compete response and a strong correlation is found with one or several of the preoperative imaging techniques, this can lead

to the further research in which patients expected to have a pathologic complete response will not undergo surgery.

Study objective

The goal of this study is to assess the efficacy of single dose preoperative radiotherapy in patients with low risk breast cancer. In this context, efficacy is the proportion of patients achieving a pathologic complete response after single dose radiotherapy. Furthermore we will investigate possible predictors of response, such as MRI and liquid biopsies, and treatment-induced toxicity.

Study design

This is a single arm interventional cohort trial.
Patients who initially fulfill inclusion criteria will undergo a diagnostic MRI scan a sentinel node biopsy. If MRI shows a unifocal tumor and sentinel node is without malignancy, the patient can be treated with single dose radiotherapy. After 1 week, and after 3, 6, 9 and 12 months a MRI will be made to assess the response, this will be combined with a consult with the radiation oncologist. After 12 months breast conserving surgery will take place. If no radiologic complete response is observed on MRI after 6 months, the breast conserving surgery will be performed earlier. If progression of the tumor is observed on MRI, breast conserving surgery will be performed as soon as possible.
Patients will be followed for a total of 10 years through mammography and physical exam.
During the entire study the patients will be asked to fill out questionnaires and cosmetic photographs of the breasts will be taken.

Intervention

MR-guided single dose preoperative radiotherapy of 20Gy to the tumor.

Study burden and risks

The burden consists of two surgeries patients have to undergo instead of one, in standard of care sentinel node biopsy and breast conserving surgery will be performed in one session. Furthermore patients have to undergo multiple MRI scans and an additional biopsy of the irradiated tumor. For patients the period between radiotherapy and surgery can be be a mental burden. The risks for patients participating in the study are similar to those of patients receiving standard of care. To keep the risk of recurrent disease to a minimum we decided to perform surgery ahead of time in case no radiologic complete response is observed at 6 months following radiotherapy.

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
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Female, ><= 50years, breast cancer, ER positive tumor, Her2 negative tumor, tumor maximum 3cm in diameter, BR grade 1 or 2

Exclusion criteria

Indication for chemotherapy, lobular carcinoma, previous breast cancer, lymph node or distant metastasis, BRCA1, BRCA2 or CHEK2 gene mutation

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-10-2018
Application type:	First submission
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
Other	Clinicaltrials.gov
CCMO	NL63209.041.18