Single-dose preoperative partial breast re-irradiation and repeat breast-conserving surgery in patients with an ipsilateral recurrent breast event

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The REPEAT trial is a feasibility trial of repeat breast-conserving therapy consisting of preoperative single-dose partial breast irradiation and breast conserving surgery to assess the rate of grade 2 or higher acute radiotherapy- and surgery-...

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

Summary

ID

NL-OMON57143

Source
ToetsingOnline

Brief title
REPEAT

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, bresat carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

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

Intervention

Keyword: breast cancer, preoperative, radiotherapy, recurrence

Outcome measures

Primary outcome

Rate of grade >= 2 acute radiation-induced toxicity within 3 months following preoperative radiotherapy and postoperative complications within 30 days using Common Terminology Criteria for Adverse Events v.5.0 (skin toxicity, breast edema, breast pain and chest wall pain) and the Clavien-Dindo Classification (wound infection)

Secondary outcome

Other acute and late radiotherapy- and surgery-associated toxicity, mastectomy rates, quality of life, cosmetic outcomes, patient satisfaction, local recurrence, regional recurrence, distant metastases, disease-free survival, breast cancer specific- and overall survival rates, radiologic and pathologic response.

Study description

Background summary

The standard of care of patients with an ipsilateral recurrent breast event is a salvage mastectomy after previous breast-conserving therapy (bresat-conserving surgery+radiotherapy). Interest in repeat brest-conserving therapy is rising in order to avoid mastectomy and improve quality of life in these patients.Several previous studies suggest that repeat BCS and post-operative re-irradiation (5-25 sessions) is safe in patients with a low-risk ipsilateral recurrent breast event. The 5-year local control rate is 76% in patients treated with repeat breast-conserving surgery alone and 89%

after repeat breast-conserving surgery followed by re-irradiation. The 5-year overall survival rates were 77% and 87%, respectively. A repeat sentinel node procedure will be performed based on the decision of the multidisciplinary tumor board of the relevant hospital according to standard of care.
Interest is also rising in preoperative PBI in patients with primary breast cancer. Preoperative radiotherapy allows a more precise and less observer-dependent definition of the target volume, and smaller irradiated volume of the breast compared to postoperative radiotherapy, which might translate in lower treatment-related toxicity and improved cosmetic outcome. In addition, smaller irradiated volumes allow a reduced number of radiotherapy sessions, to even a single-dose radiotherapy. Thus, it is highly relevant to explore whether preoperative PBI can also be applied in the recurrent low-risk setting.

Study objective

The REPEAT trial is a feasibility trial of repeat breast-conserving therapy consisting of preoperative single-dose partial breast irradiation and breast conserving surgery to assess the rate of grade 2 or higher acute radiotherapy- and surgery-induced toxicity. In addition, tumor response will be assessed using MRI, tumor tissue and blood. Toxicity, patient-reported outcome measures, cosmetic results and oncological outcomes prior to, during and following treatment will be evaluated.

Study design

This is a single-arm prospective cohort study. Patients who fulfill the inclusion criteria will be treated with single-dose partial breast irradiation. After 3 weeks a preoperative MRI-scan will be performed to assess acute tumor response. Prior to and 3 weeks after radiotherapy, blood samples will be taken voor response monitoring. After 3 weeks breast-conserving surgery will be performed. A repeat sentinel node procedure will be performed based on the decision of the multidisciplinary tumor board of the relevant hospital according to standard of care. A consultation at the outpatient department with physical examination will take place 2, 6 and 12 weeks after treatment. Patients will be followed for a total of 5 years through mammography and physical examination. During the entire study, the patients will be asked to fill out questionnaires to evaluate patient-reported outcomes including quality of life and cosmetic outcome. In addition, toxicity will be evaluated and digital photographs of the breasts will be taken to evaluate cosmetic outcome.

Intervention

Single dose preoperative radiotherapy of 20 Gy to the tumor

Study burden and risks

The burden for participating patients consists of 1 additional MRI-scan, two additional blood samples and one optional additional tumor biopsy. The additoinal blood samples will be combined with placing IV entrance for the MRI-scan. The additional biopsy can be combined with marker insertion, which is standard of care. The patient can give additional consent for the biopsy.
Furthermore, 10 questionnaires are filled out by the patients for evaluation of patient-reported outcomes, toxicity and cosmetic outcome.
Breast-conserving surgery will be less burdensome than the standard mastectomy. The first surgery is in day care, while for the mastectomy the patient is submitted in the hospital for another day.
The treatment burden of a single-dose preoperative PBI is reduced compared to standard postoperative multiple-fractionated re-irradiation (i.e. 5-25 sessions).

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, 50 years or older, ipsilateral recurrent invasive breast cancer tumor size <= 2 cm, unifocal on MRI, Bloom Richardson grade 1 or 2, ER-positive tumor, HER2-negative tumor, non-lobular, clinical node negative on PET-CT/ultrasound/MRI, no distant metastasis, repeat breast-conserving surgery is feasible due to no or mild late toxicity from previous breast-conserving therapy

Exclusion criteria

Ipsilateral breast cancer event less than 2 years after first breast-conserving therapy, other malignancy within 5 years before ipsilateral bresat recurrence diagnosis, bresat cancer mutation gene carrier, previous ipsilateral mastectomy, MRI contra-indication, indication for neoadjuvant chemotherapy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2024
Enrollment:	25
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-10-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL85983.018.24