An integrated optimization of Surgery and radioTherApy techniques to impRove cosmetic outcome and quaLity of life In breast conserviNG therapy for breaSt cancer patient

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22078

Source
NTR

Brief title
STARLINGS study

Health condition

Breast cancer

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Stichting BeterKeten

Intervention

Outcome measures

Primary outcome

The primary focus of this project will be to determine which different combinations of (oncoplastic reconstructive) surgery and radiotherapy techniques, in the context of breast conserving therapy for (pre-invasive) breast cancer, contribute the most to the development of fibrosis.

Secondary outcome

To assess the relation between the presence and severity of fibrosis, cosmetic outcome and different QoL domains and symptoms.

Study description

Background summary

One in seven women will be diagnosed with breast cancer at some point during life. The majority of patients (60-70%) can be treated with breast conserving therapy consisting of lumpectomy (instead of mastectomy) combined with a sentinel node procedure or axillary lymph node dissection, followed by irradiation of the breast. A lot of patients also receive chemotherapy.
As life expectancy after breast cancer treatment has become substantially longer due to improved multimodality treatment, late adverse effects of the treatment affecting quality of life (QoL) have become increasingly important. Unfortunately, breast fibrosis occurs as a late adverse event in a substantial subset of patients (10-30%) after breast conserving therapy for DCIS or breast cancer. Fibrosis can be painful and may result in poor cosmetic outcome. Fibrosis as well as poor cosmetic outcome can negatively affect QoL. Besides patient and tumor related factors, both surgery and radiotherapy play a role in the risk of developing fibrosis.
Both surgical and radiation oncologists aim for the best cosmetic outcome and QoL of each patient, without compromising oncological safety. However, especially in the light of current oncoplastic reconstructive surgery techniques, it has not yet been properly investigated how the different surgery and radiotherapy techniques interact.
The primary focus of this project will be to determine which different combinations of (oncoplastic reconstructive) surgery and radiotherapy techniques, in the context of breast conserving therapy for (pre-invasive) breast cancer, contribute the most to the development of fibrosis. Second, to assess the relation between the presence and severity of fibrosis, cosmetic outcome and different QoL domains and symptoms.

Study objective

Surgical and radiation oncologists aim for the best cosmetic outcome and QoL of each patient, without compromising oncological safety. However, especially in the light of current oncoplastic reconstructive surgery techniques, it has not yet been properly investigated how the different surgery and radiotherapy techniques interact.

Study design

4-6 years after treatment (1 time point)

Contacts

Public
Erasmus MC
C. (Marije) A.W. Notenboom

010 704 11 16
Scientific
Erasmus MC
C. (Marije) A.W. Notenboom

010 704 11 16

Eligibility criteria

Inclusion criteria

• Female patients aged ≥ 18 years
• History of BCT with adjuvant radiation therapy for non-metastatic, histologically proven invasive breast cancer (pT1-3N0-2a) or DCIS. In light of BCT adjuvant systemic treatment (i.e. endocrine therapy, chemotherapy and immune therapy) is allowed.
• Breast conserving surgery between 1st of January 2016 and 31th of December 2018
• Treated according to the currently applied dose fractionation schedules, i.e. whole breast radiotherapy, with or without boost
• Adequate understanding of the Dutch language and written informed consent

Exclusion criteria

• Any breast surgery or re-irradiation on the breast area after BCT
• Progression of disease (and additional treatment) since BCT
• Patients who received partial breast irradiation
• Current pregnancy or breast feeding

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-09-2021
Enrollment:	750
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9840
Other	METC Erasmus MC : MEC-2021-0829

Study results