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

Gepubliceerd: 27-10-2021 Laatst bijgewerkt: 13-12-2022

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…

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22078

Bron
NTR

Verkorte titel
STARLINGS study

Aandoening

Breast cancer

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Stichting BeterKeten

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

4-6 years after treatment (1 time point)

Contactpersonen

Publiek

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

010 704 11 16

Wetenschappelijk

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

010 704 11 16

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	20-09-2021
Aantal proefpersonen:	750
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9840
Ander register	METC Erasmus MC : MEC-2021-0829

Resultaten