“Association of Radiation-induced Lymphocyte Apoptosis with Radiation Induced Fibrosis after Breast Conserving Therapy”

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We hypothesize that among breast cancer patients with a grade 3 breast fibrosis the RILA frequency is significantly lower compared to the RILA frequency among breast cancer patients with no fibrosis.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21812

Bron
NTR

Verkorte titel
RILARIF

Aandoening

Radiation Induced Fibrosis, Breast Cancer

Ondersteuning

Primaire sponsor: Erasmus MC Cancer Institute, Dpt. of Surgical Oncology
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to assess the association between RILA frequency and RIF after BCT and radiotherapy among breast cancer patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Around 5% of all patients treated with breast conserving therapy (BCT) are affected by a severe form of radiation-induced fibrosis (RIF) of the treated breast. RIF is characterized by reduced tissue flexibility, reduced compliance or stricture. There is a large patient-to-patient variability of being at risk for RIF. The severity of RIF is known to be affected by differences in treatment characteristics and individual radiosensitivity. An important biological difference associated with differences in individual radiosensitivity, is the presence of senescence in cells. Senescence is a permanent arrest state of the cell division. Senescence can be induced by Ionizing Radiotherapy (IR) in fibroblasts and other cellular types. The senescence characteristic of reduced apoptosis can possibly be used to assess the risk of RIF. The risk of RIF was reported to show a positive correlation with reduced apoptosis in the Radiation-Induced Lymphocyte Apoptosis (RILA) assay. Previous studies have shown that a low RILA frequency is associated with a higher risk of developing RIF. The Primary objective of this study is to assess the univariate association between RILA frequency and RIF after BCT among breast cancer patients. We hypothesize that among breast cancer patients with a grade 3 breast fibrosis the RILA frequency is significantly lower compared to the RILA frequency among breast cancer patients with no fibrosis.

Doel van het onderzoek

We hypothesize that among breast cancer patients with a grade 3 breast fibrosis the RILA frequency is significantly lower compared to the RILA frequency among breast cancer patients with no fibrosis.

Onderzoeksopzet

After inclusion, patients will be invited for a one-off hospital visit for blood withdrawal, skin punch biopsy and questionnaires.

Onderzoeksproduct en/of interventie

• Two 5-ml heparinized blood samples
• Skin punch biopsy

• Three HRQoL questionnaires (BREAST-Q, postoperative BCT module; EORTC QLQ-C30 and BR23)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Aged ≥ 18 years
• History of BCT with radiation therapy for non-metastatic, histologically proven invasive breast cancer (pT1-3N0-2a)
• Having ≥ grade 3 fibrosis on the LENT SOMA scale (cases)
• Having with ≤ grade 1 fibrosis on the LENT SOMA scale (controls)
• Adequate understanding of the Dutch or English language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Male patients
• Patients who are unable to provide written informed consent or fill out the questionnaires

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	02-11-2020
Soort:	Eerste indiening

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	NL9020
Ander register	METC Erasmus Medical Centre : MEC2020-0484

Resultaten

Samenvatting resultaten
N/A