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

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49154

Source
ToetsingOnline

Brief title
RILARIF

Condition

- Other condition
- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
radiation induced fibrosis

Health condition

Radiation induced fibrosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Lymphocyte apoptosis, Radiation induced fibrosis

Outcome measures

Primary outcome

The primary study outcome is the frequency of radiation-induced apoptosis of

CD4+ and CD8+ T-lymphocytes in cases and controls.

Secondary outcome

The secondary study outcomes are treatment and patient related risk factors and

health related quality of life.

Study description

Background summary

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.

Study objective

The primary objective of this study is to assess the univariate association between RILA frequency and RIF after BCT and radiotherapy among breast cancer patients. Secondary objectives include: the identification of treatment and patient related risk factors of developing RIF and the assessment of the association between RIF and Patient Reported Outcomes (PROs).

Study design

Single center non-matched case-control study

Study burden and risks

The burden for the subject will be in proportion to the potential value of the research. There will be only one visit with a maximum of one hour to the outpatient clinic to collect two blood samples and one skin biopsy in the inframammary fold. A minimal risk of side effects of the blood sample and skin biopsy is expected. This includes limited pain and hematoma at the biopsy or venipuncture side. There is a very low risk of infection and hemorrhage after biopsy. The biopsy side may feel uncomfortable the first days. Also, three well validated one-time questionnaires (EORTC QLQ-C30, EORTC QLQ-BR23 and BREAST-Q) will be used to assess the QoL of the participants. The QoL questionnaires will take 20-25 minutes in total and subjects will complete the questionnaires in their own time and space.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
Rotterdam 3015 GD
NL

Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Females and age 18 years or older
History of BCT with radiation therapy for non-metastatic, histologically proven invasive breast cancer (pT1-3N0-2a)
Having either * grade 1 (controls) or * grade 3 (cases) fibrosis on the LENT SOMA scale

Exclusion criteria

Males

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-08-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL74017.078.20