Breast edema after breast-conserving surgery and radiotherapy

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23137

Source
Nationaal Trial Register

Health condition

In contrast to arm morbidity which is thoroughly described in literature, only a few studies investigated breast morbidity after breast cancer treatment. Currently, there is no consensus on the definition of breast edema and on standardized assessment criteria. Common criteria found in literature are an increased volume of the breast, peau d’orange, heaviness of the breast, redness of the skin, breast pain, skin thickening, hyperpigmented skin pores and a positive pitting sign.

Sponsors and support

Primary sponsor: Faculty of Medicine and Health Sciences, department of rehabilitation sciences and physiotherapy, MOVANT research group, Universiteitsplein 1, 2610 Wilrijk, Belgium
Source(s) of monetary or material Support: Faculty of Medicine and Health Sciences, department of rehabilitation sciences and physiotherapy, MOVANT research group, Universiteitsplein 1, 2610 Wilrijk, Belgium

Intervention

Outcome measures

Primary outcome

The breast edema questionnaire consists of 2 parts. In the first part, symptoms of breast edema such as described in literature are scored on a scale from 0 to 10: pain, heaviness, swelling, tensed skin, redness, pitting sign, enlarged skin pores and hardness. Taking into account the ICF (International Classification of Functioning, disabilities and health), a number of activities and participations are scored on a scale from 0 to 10. This is part 2 of the questionnaire. In both parts a higher score means more problems related to breast edema.

Secondary outcome

The McGill Quality of Life Questionnaire is used to assess the impact of breast edema on the quality of life.

Study description

Background summary

The aim of the project is to prospectively assess the incidence and time path of breast edema in patients that are treated with breast conserving surgery in combination with radiotherapy. Additionally, the impact of breast edema on physical functioning (ICF-framework) and QoL will be investigated. Breast cancer patients will be recruited from the Iridium-network at the moment the simulation for radiotherapy is planned. Next, the patients are assessed prospectively: 1) at the end of radiotherapy (after last session), 2) every 3 months until 18 months of follow-up is established. The primary outcome measures are incidence of breast edema based upon a breast edema questionnaire and QoL by means of the Dutch McGill-QoL qiuestionnaire. Secondary, medical data will be related to the development of breast edema.

Study objective

Breast-conserving surgery followed by radiotherapy is a safe and effective procedure to treat early stage breast cancer. In many women, this type of treatment gives beside a good survival a good cosmetic result. However, some women will be troubled by breast edema. Breast edema causes a great discomfort during activities of daily living and has a negative impact on quality of life. Although breast edema is a common, debilitating complication of breast-conserving surgery, it is still strongly underrecognized in clinical practice.

Study design

Before radiotherapy, after radiotherapy, 3 months, 6 months and 12 months after radiotherapy

Intervention

Patients who underwent breast-conserving surgery in one of the hospitals of the Iridium

network, report in the St. Augustinus Hospital to the Radiotherapy Department for a simulation. Patients are informed about the study. If they wish to participate they are asked to fill out a consent form. During this first contact, the patient fills out the breast edema questionnaire and the Mc Gill Quality of Life questionnaire. Afterwards, the same questionnaires were sent by mail at fixed intervals: after the completion of radiation therapy and 3 months, 6 months and 12 months after radiotherapy. A stamped envelope is also sent, so the patient can return the completed questionnaire.

Contacts

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Eligibility criteria

Inclusion criteria

- Women

- Unilateral breast-conserving surgery

- Radiotherapy

- Between 18 and 65 years old

Exclusion criteria

- Only mammotome biopsies

- Other disorders which can cause breast edema

- Plastic surgery such as mammoplasty in patients with macromastia

- Pregnany

- Lack of understanding of the Dutch language

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	15-03-2017
Enrollment:	200
Type:	Unknown

Ethics review

Positive opinion

Date:	17-03-2017
Application type:	First submission

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	NL6343
NTR-old	NTR6527
Other	Ethical Comite of the University Hospital of Antwerp : B300201317503

Study results