Set-up and intra-fractional motion management for breast cancer patients.

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The aim of the study is to improve the positioning of patients who are irradiated on the breast. Optical surface scanning will be used and the precision, patient friendliness, and process optimization are studied.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON55666

Source
ToetsingOnline

Brief title
Positioning of breast cancer patients

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
'breast cancer', 'breast tumor'

Research involving
Human

Sponsors and support

Primary sponsor: Dr. Bernard Verbeeten instituut
Source(s) of monetary or material Support: deels door fondswerving van Stichting Verbeeten Fonds en deels door Instituut Verbeeten.

Intervention

Keyword: Intra-fraction motion, Optical surface scanning, Radiotherapy, Real-time monitoring

Outcome measures

Primary outcome

Rate of success of the set-up.

Secondary outcome

Number of images and displacement of the couch are secondary study parameters.

Study description

Background summary

A radiation therapy treatment requires a precise and reproducible position and posture of the patient on the treatment couch. It is important that motion of the patient is avoided during the treatment. The current method consists of tattoos on the skin of the patient, which are used to set-up the patient. In this study optical surface scanning is used to position the patient. An optical surface scanner creates a 3D image of the patient and can be used to improve the positioning of patients and to perform intra-fractional motion management. During irradiation of the breast, patients hold their breath, hence the distance from the heart to the thorax wall is maximized and the heart will receive less radiation. Optical surface scanning is also use to monitor this breath-hold.

Study objective

The aim of the study is to improve the positioning of patients who are irradiated on the breast. Optical surface scanning will be used and the precision, patient friendliness, and process optimization are studied.

Study design

This study is a clinical feasibility study. Clinical feasibility in this study is defined when more than 80% of the patients are positioned successfully by using optical surface scanning. A successful set-up is determined by measuring the angle of the clavicle on the online made image. All subjects participating in the study receive local or locoregional breast irradiation and optical

surface scanning is used for set-up and breath-hold monitoring.

Intervention

The intervention in this study concerns the treatment method of local or locoregional breast irradiation; the treatment itself is the same whether patients participate in the study or not. Patient set-up is performed using optical surface scanning and the tattoo points are not required any more. As is common with radiotherapy of the breast, online imaging is used for a reproducible inter-fractional position of the patient. For intra-fractional breath-hold monitoring an optical surface scanner is used. The therapists can see the depth of the breath hold on a screen. Patients are instructed to repeat the breath-hold procedure, if necessary. The surface scanner used for this study is IDENTIFY (HumediQ/Varian), which constructs a 3D-reconstruction of a subject. The actual position of the patient is compared to a daily made reference image and the deviation is presented on a screen.

Study burden and risks

Participation in the study means subjects are positioned using a new method, consisting of optical surface scanning. The advantage for patients is that tattoo points on the skin are not needed. Another advantage can be that the positioning will be faster and more precise. Side effects of the radiation treatment can occur. These effects do not differ whether a patient participates in the study or not.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* The therapy consists of local or locoregional breast irradiation with voluntary moderate deep inspiration breath-hold.
* The patient is willing to travel to Tilburg for the treatment.
* The patient is motivated and willing to be involved in radiation therapy using surface scanning for positioning and motion monitoring.
* The patient is competent enough to understand the Dutch language to follow up instructions of the radiation technologist.

Exclusion criteria

Males are excluded from participation in the study. Patients where bolus material is necessary to achieve sufficient skin dose are excluded as well. Patients who are irradiated at more than one treatment site are also excluded and patients who are treated with the FAST(-Forward) schedule are excluded.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2020
Enrollment:	85
Type:	Actual

Medical products/devices used

Generic name:	IDENTIFY
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-05-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	11-03-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	03-11-2020
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	27-01-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL69214.028.19