Pilot study on the use of a radiopaque hydrogel during breast conserving surgery with full-thickness closure for target definition and positioning of boost or partial breast irradiation.

Published: 20-06-2017
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Primary objective: Estimate the Conformity Index (Cx) of target definition. Secondary objectives: Estimate the distance between the center of mass (dCOM) of the observers* target volumes, Cavity Visualisation Score (CVS), feasibility of the hydrogel...

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

Summary

ID

NL-OMON47859

Source
ToetsingOnline

Brief title
Target study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
breast cancer, breast carcinoma

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: breast neoplasms, full thickness closure, hydrogel, Radiotherapy Target Organ Alignment

Outcome measures

Primary outcome

primary endpoint: the Conformity Index (Cx) of target definition.

Secondary outcome

Secondary endpoints: the distance between observers* target volumes (dCOM),

target volumes, Cavity Visualisation Score, feasibility of the hydrogel marker

instillation, stability of the hydrogel marker volume over time, adverse

events, ease of use, motion of hydrogel marker/clips over time, the feasibility

of patient positioning based on the hydrogel marker on cone beam computed

tomography (CBCT) and planar kV images made on a conventional linac and a

Cyberknife and the accuracy of this procedure compared to positioning based on

the surgical clips.

Study description

Background summary

Breast conserving surgery (BCS) followed by breast radiotherapy has been shown to be as effective as ablative therapy in the treatment of early stage breast cancer patients. In BCS there is a shift towards the use of full-thickness closure (FTC), or oncoplastic techniques in general. This development creates challenges in breast radiotherapy target definition. Quality of target definition for radiotherapy after FTC is imprecise. We hypothesize that

instillation of a radiopaque hydrogel during FTC of the lumpectomy cavity will reduce inter-observer variability during target definition for boost or partial breast irradiation. Also, we hypothesize that it will increase the accuracy of patient positioning during radiation delivery.

Study objective

Primary objective: Estimate the Conformity Index (Cx) of target definition. Secondary objectives: Estimate the distance between the center of mass (dCOM) of the observers* target volumes, Cavity Visualisation Score (CVS), feasibility of the hydrogel marker instillation, stability of the hydrogel marker volume over time, comparison of target volumes defined by clips and hydrogel, adverse events, ease of use, motion of hydrogel marker/clips over time, the feasibility of patient positioning based on the hydrogel marker on cone beam computed tomography (CBCT) and planar kV images made on a conventional linac and a Cyberknife and the accuracy of this procedure compared to positioning based on the surgical clips.

Study design

Cross sectional interventional study, with a retrospective matched control group, on the inter-observer variability of 6 measures applied to 60 patients across 5 observers. All 5 observers will rate all 60 patients. Interventional group of 20 patients will get hydrogel + clips. Matched control group of 40 patients gets standard clips only. The positioning accuracy will be assessed in a subset of 10 patients from the intervention group. Study will be performed combined in a large secondary hospital (Franciscus Gasthuis, Rotterdam) and a tertiary hospital (Erasmus MC, Rotterdam)

Intervention

5-10ml of Iodined PolyEthyleneGlycol, brandname *TraceIT* will be left behind just before FTC by stepwise instillation and coating the lumpectomy cavity walls. All patients will undergo a CT at 3 times (post-op (day of surgery), 4 weeks (regular planning CT), and 2.5± 0.5months). In addition, for research purposes regular CBCT images that monitor the patient positioning during radiotherapy will be used. Optionally, patients undergo a test session at the CyberKnife.

Study burden and risks

Tolerance of the investigational product is expected to be good based on existing safety data. Radiation dose of the extra study images is negligible with regards to total radiation dose of the radiotherapy treatment. Furthermore, target definition and patient positioning may be improved by this new technique, with possibly lower radiation dose to healthy tissue and fewer

geographical misses. We conclude that the benefits of the treatment when used as intended considerably outweigh the risks.

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

* Woman
* Undergoing breast conserving surgery
* Indication for radiotherapy
* Full thickness closure (level 1 oncoplastic breast surgery) planned
* Written informed consent

Exclusion criteria

* Oncoplasty technique (level 2 Oncoplastic breast surgery) planned
* need for adjuvant chemotherapy
* Allergy for PEG
* Allergy for Iodine

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	TraceIT hydrogel
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-06-2017

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-04-2018
Application type:	Amendment
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	NL61639.078.17
Other	NTR6610.