Comparison of post-RFIB and post-operative clinical target volumes in breast-conserving therapy: A prospective cohort study

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To compare Clinical Target Volumes after RFIB (CTV-RFIB) and after BCS (CTV-POC).

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

Summary

ID

NL-OMON35489

Source
ToetsingOnline

Brief title
Post-RFIB and post-operative clinical target volumes.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mammary malignancy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Breast cancer, Radiofrequency-assisted intact specimen biopsy., Radiotherapy, Target volume

Outcome measures

Primary outcome

CTV-RFIB and CTV-POC.

Secondary outcome

Not applicable.

Study description

Background summary

In DCIS and early-stage breast cancer patients, breast-conserving therapy is today*s standard of care. Breast-conserving therapy consists of breast-conserving surgery (BCS) and radiotherapy (RT). Besides tumor excision by the surgeon, a margin of breast tissue surrounding the tumor has to be treated by the surgeon and radiation oncologist due to the potential presence of additional microscopic tumor foci. Therefore, post-operatively, a radiotherapy (RT) planning CT scan is performed, and the excisional area, called the post-operative complex (POC), has to be identified. This POC has to be irradiated with a 1.5 cm margin, minus the minimal tumor free margin (as described in the pathology report). This is called the Clinical Target Volume (CTV).
Recently, a new breast-biopsy procedure called Radiofrequency-assisted Intact Specimen Biopsy (RFIB) has been introduced in the UMC Utrecht. Besides a higher diagnostic accuracy, this method has shown the potential of radical excision of small breast tumors. In the future, RFIB might be used as a minimally invasive therapeutic procedure in selected breast cancer patients. A radical RFIB procedure always has to be followed by RT. Therefore, we will observe the change in RT target volumes after RFIB. The biopsy specimens are small, but the excision cavity walls are not approximated as in BCS. Large target volumes are associated with worse cosmetic result and a higher dose in surrounding organs which can result in an increased risk of lung and cardiovascular disease.

Study objective

To compare Clinical Target Volumes after RFIB (CTV-RFIB) and after BCS

(CTV-POC).

Study design

Prospective cohort study, using CT imaging

Study burden and risks

Patients will undergo one additional CT scan preoperatively. The effective dose equivalent of this CT scan is approximately 0.10 Sv. Considering the radiation dose delivered to the ipsilateral breast (42,56 / 50 Gy) and its scattered dose to adjacent structures, the risk of one additional CT scan will be marginal. This CT scan ideally will be scheduled in combination with another in-house pre-operative appointment. When an additional visit to the hospital is required, patients will receive reimbursement of travelling expenses. For the patients included in the study there is no individual benefit.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Female gender;
- Age >=18
- cTis-T1N0 breast cancer;
- RFIB procedure showing microscopically tumor free resection margins
- Scheduled for breast-conserving therapy (BCS + WBRT);
- Before breast-conserving surgery;
- Written informed consent.

Exclusion criteria

- Legal incapability;
- Insufficient command of the Dutch language;
- Inability to maintain the standard supine RT treatment position for 30 minutes;
- Treated with neo-adjuvant systemic therapy;
- Treated with a modified radical mastectomy or breast amputation.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	14-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24565
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL38117.041.11
OMON	NL-OMON24565