

TOP-1: Omission of radiotherapy in elderly patients with low risk breast cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24515

Source

Nationaal Trial Register

Brief title

TOP-1

Health condition

Elderly, Breast, Cancer, Radiotherapy

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)

Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Outcome measures

Primary outcome

Primary aim: to assess whether radiotherapy can be safely omitted after breast conserving surgery in elderly patients with a very low risk of local recurrence

Secondary outcome

Secondary aim: assessment of: quality of life, toxicity, geriatric assessment, overall- and breast cancer specific survival, distant metastasis free survival, relating biomarkers to outcome (tumor characteristics, at least: IHC ER, PR, HER2 and Ki-67), additional state of the art molecular analysis if possible, development and validation of local recurrence rate prediction models, (cost) efficacy (comparison with historical control group) and implementation of findings into standard care

Study description

Background summary

The main focus of the present trial is a first step towards treatment de-escalation in older breast cancer patients.

Primary aim: to assess whether radiotherapy can be safely omitted after breast conserving surgery in elderly patients with a very low risk of local recurrence.

Secondary aim: assessment of: quality of life, toxicity, geriatric assessment, overall- and breast cancer specific survival, distant metastasis free survival, relating biomarkers to outcome (tumor characteristics, at least: IHC ER, PR, HER2 and Ki-67), additional state of the art molecular analysis if possible, development and validation of local recurrence rate prediction models, (cost) efficacy (comparison with historical control group) and implementation of findings into standard care.

Study objective

Radiotherapy (RT) can safely be omitted after breast conserving surgery (BCS) in elderly patients at low risk of developing a local recurrence (LR)

Study design

The primary endpoint is the local recurrence rate (LRR) at 5 years. Secondary determinants are the distant metastases free survival (DMFS), breast cancer-specific survival (BCSS) and overall survival (OS)

Intervention

Omitting adjuvant radiotherapy

Contacts

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Eligibility criteria

Inclusion criteria

1. Low-risk invasive breast cancer: tumour < 1 cm, grade 1-2 or tumour 1-2 cm, grade 1
2. Registration within 3 months after Breast Conserving Surgery
3. R0 resection
4. HER2 negative
5. pN0 or pN0(itc) disease
6. ER positive > 50%
7. Age ≥ 70 years
8. Indication for standard radiotherapy
9. Willing to complete quality of life questionnaires and geriatric assessments
10. Female

Exclusion criteria

1. Indication for hormonal therapy
2. Bilateral

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2016
Enrollment:	1200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	24-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53002
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5983
NTR-old	NTR6147
CCMO	NL58117.058.16
OMON	NL-OMON53002

Study results