

Tailored treatment in Older Patients

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

Published: 23-11-2016

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53002

Source

ToetsingOnline

Brief title

TOP-1

Condition

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

Synonym

breast cancer, breast malignancy

Health condition

radiotherapie

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, KWF

Intervention

Keyword: breast, cancer, elderly, radiotherapy

Outcome measures

Primary outcome

The primary endpoint is the local recurrence rate (LRR) at 5 years.

Secondary outcome

Secondary determinants are the distant metastases free survival (DMFS), breast cancer-specific survival (BCS) and overall survival (OS), quality of life, side-effects, costs, cosmetic outcome, geriatric assessment and biomarkers

Study description

Background summary

Breast cancer is the most common cancer type in women of 70 years and older, accounting for over 4.000 patients per year in the Netherlands. The benefit of standard adjuvant treatments in older patients with breast cancer are limited and influenced by both patient related factors as well as tumor related factors. Preventing over-treatment is therefore pivotal for these patients, allowing reduced treatment burden, improved quality of life and cost efficacy. However, in clinical practice, older women are mostly treated according to general standards, not taking into account age specific factors. The Dutch TOP consortium (Tailored treatment in Older Patients) aims at tailoring treatment of older women with breast cancer by allocating treatment to those patients who will benefit and to prevent overtreatment in all others. Previous studies, including the recent PRIME-II study, showed that omitting radiotherapy after breast conserving surgery in older patients is safe and does not result in decreased survival. Despite these results, currently, 98% of

older patients with low risk breast cancer (obviating the need for adjuvant systemic therapy) in the Netherlands, still receive adjuvant radiotherapy after breast conserving surgery.

Study objective

The main focus of the present proposal is a first step towards treatment intensity de-escalation in older breast cancer patients. For this, we propose to initiate the first TOP consortium study (TOP-1) that will study the effect of omitting radiotherapy in elderly women with early stage breast cancer after breast conserving surgery.

Study design

TOP-1 is a national, multicenter, non-randomized, single-arm, prospective cohort study.

Intervention

These patients will not receive adjuvant radiotherapy.

Study burden and risks

The immediate impact for 95% of the TOP-1 participants is to be justly spared intensive radiotherapy and subsequent risk of side effects (such as fatigue, possible lung and cardiac damage). The other 5% will develop a local recurrence, which would not have happened with standard radiotherapy (3-fold of this risk, from 2.5% to 7.5% at five years). The majority of these recurrences can however effectively be treated with salvage surgery and previous studies showed that patient survival will likely not be affected. This limited risk of local recurrence increase for this particular patient population was deemed acceptable following consultation with patient advocates.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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:

- age 70 years and older;
- after breast conserving surgery
- tumor <1cm grade 1-2 or tumor 1-2cm grade 1;
- tumor ER>50% positive, HER2 negative;
- sN0 or sN0(itc);
- R0 resection;
- female.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- indication for hormonal therapy;
- bilateral.

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): 12-01-2017

Enrollment: 1200

Type: Actual

Ethics review

Approved WMO

Date: 23-11-2016

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 20-01-2017

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 10-03-2017

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 12-04-2017

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 26-04-2017
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 02-05-2017
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 10-07-2017
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 06-10-2017
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 12-01-2018
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 08-02-2018

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 04-12-2018
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 18-01-2019
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 24-04-2019
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 25-09-2019
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 10-08-2020
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 28-01-2022

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 24-06-2022
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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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: 24515
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58117.058.16