DESCARTES trial: De-ESCAlating RadioTherapy in patients with pathologic complete rESponse to neoadjuvant systemic therapy.

Published: 27-01-2022
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Primary aim: to assess whether local recurrence is acceptable when radiotherapy is omitted after breast conserving surgery in patients treated with NAC who achieve a pathologic complete response.Secondary aim: to assess quality of life and cancer...

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

Summary

ID

NL-OMON56100

Source
ToetsingOnline

Brief title
DESCARTES trial

Condition

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

Synonym
Breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Antoni van Leeuwenhoek

Intervention

Keyword: Breast cancer, De-escaltion of local therapy, Neoadjuvant systemic therapy, Pathologic complete response

Outcome measures

Primary outcome

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

Secondary outcome

Secondary determinants are local non-salvageable recurrence free survival,

quality of life, regional recurrence rate, distant recurrence free survival,

disease-specific survival and overall survival.

Study description

Background summary

Over 60% of the women who are diagnosed with breast cancer in the Netherlands are treated with systemic treatment, which may be administered before (neoadjuvant chemotherapy, NAC) or after (adjuvant) locoregional treatment. Depending on the subtype, 10-75% of patients will have a pathologic complete response (pCR) after NST. In this patient group, risk of local recurrence is extremely low. The administration of adjuvant radiotherapy in these patients is not expected to contribute significantly to overall survival, but may cause considerable morbidity.

Study objective

Primary aim: to assess whether local recurrence is acceptable when radiotherapy is omitted after breast conserving surgery in patients treated with NAC who achieve a pathologic complete response.
Secondary aim: to assess quality of life and cancer worry after omitting

radiotherapy.

Study design

DESCARTES is a national, multicentre, non-randomized, single-arm prospective cohort study.

Study burden and risks

The immediate impact for participants is to be spared intensive radiotherapy and subsequent risk of side effects (such as pain, fatigue, possible lung damage). An expected 4% will develop a local recurrence within 5 years, about half of which would not have happened with standard radiotherapy. The majority of these local recurrences can however effectively be treated with salvage breast-conserving or ablative surgery and previous studies indicated that patient survival will not be affected.

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

• Women, aged >= 18 years
• Invasive HR positive/Her2 negative, Her2+ (ER/PR +/-) or TN breast cancer
• Concurrent DCIS in pre-NST biopsy is allowed if there is no suspicion of extensive component i.e. absence of non-mass enhancement on pre-NST MRI (if performed) and/or absence of calcifications on pre-NST mammography
• Primary tumour (T) clinical stage cT1-2
• Unifocal disease; confirmed by pre-NST MRI, contrast-enhanced mammography or breast-specific gamma imaging
• Clinical nodal stage 0; absence of lymph node metastases should be confirmed by ultrasound or FDG-PET/CT
• Neoadjuvant systemic treatment (NST)
• Marker placed in breast tumour prior to NST
• Breast conserving surgery performed, i.e. no mastectomy
• Sentinel node biopsy performed before or after NST
• Pathologic complete response in breast and lymph nodes, i.e. no residual tumour cells or DCIS detected
• Written informed consent

Exclusion criteria

• Primary tumour (T) clinical stage cT3-4
• Pre- or post-NST diagnosis of nodal disease including isolated tumour cells
• Concurrent LCIS of any type in either pre-NST biopsy or surgical specimen
• Patients without axillary ultrasound or FDG-PET/CT pre-NST
• History of breast cancer DCIS or LCIS
• Synchronous contralateral breast cancer DCIS or LCIS
• Synchronous M1 disease
• Carrier of gene mutation associated with increased risk of breast cancer, i.e. BRCA1, BRCA2, CHEK2, TP53 or PALB-2

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-10-2022
Enrollment:	595
Type:	Actual

Ethics review

Approved WMO Date:	27-01-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	30-03-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-05-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-06-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-10-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-12-2022

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-07-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-12-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-10-2024
Application type:	Amendment
Review commission:	METC NedMec

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
ClinicalTrials.gov	NCT05416164
CCMO	NL79099.031.21