ASICS trial: Avoiding Sentinel lymph node biopsy In select Clinical node negative breast cancer patients after neoadjuvant Systemic therapy

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The primary objective is to evaluate whether SLNB can safely be omitted in breast cancer patients with HER2+ or TN tumors who achieve rCR on MRI after NST. Secondary, quality of life will be assessed in patients with and without SLNB.

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

Summary

ID

NL-OMON48085

Source
ToetsingOnline

Brief title
ASICS 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: Axillary lymph nodes, Breast cancer, Neoadjuvant systemic therapy, Sentinel node

Outcome measures

Primary outcome

The primary endpoint is axillary recurrence after 5 years. Previous data indicate a 5-year axillary recurrence rate of 1-3% in cN0 patients who underwent NST. An upper margin of 5% axillary recurrences is considered an acceptable extent of clinical non-inferiority.

Secondary outcome

Secondary endpoints are quality of life (specifically axillary morbidity and level of cancer worry), recurrence free survival (RFS), distant metastasis-free survival, disease-specific survival and overall survival.

Study description

Background summary

Axillary staging in clinically node negative (cN0) breast cancer patients with neoadjuvant systemic therapy (NST; i.e. chemo- and immunotherapy), is preferably performed with sentinel lymph node biopsy (SLNB) after NST. The probability of a tumor-positive SLNB post-NST is low. cN0 patients with Human Epidermal growth factor Receptor 2- positive (HER2+) or triple negative (TN) breast cancer who achieve radiologic complete response (rCR) of the breast on MRI, have the lowest probability of a tumor-positive SLNB post-NST (<3%). Omitting removal of axillary lymph nodes in clinically node negative patients does not increase the rate of distant metastases nor breast cancer mortality. Performing SLNB can cause short- and long-term morbidity, reducing quality of life. The additional value of performing SLNB in patients with a very low risk

of tumor-positive axillary lymph nodes should be investigated. Therefore, we designed the ASICS trial: Avoiding Sentinel lymph node biopsy In select Clinical node negative breast cancer patients after neoadjuvant Systemic therapy.

Study objective

The primary objective is to evaluate whether SLNB can safely be omitted in breast cancer patients with HER2+ or TN tumors who achieve rCR on MRI after NST. Secondary, quality of life will be assessed in patients with and without SLNB.

Study design

The ASICS trial (Avoiding Sentinel lymph node biopsy In select Clinical node negative breast cancer patients after neoadjuvant Systemic therapy) is a prospective non-inferiority registration trial investigating the safety of omitting SLNB after NST in cN0 patients with HER2+(hormone receptor [HR] +/-) or TN tumors who achieve rCR on MRI after NST. The primary endpoint is axillary recurrence after 5 years. The important secondary endpoint is quality of life (specifically axillary morbidity and level of cancer worry), measured with the questionnaires EORTC QLQ-BR23 and EORTC QLQ-C30, and the cancer worry score, pre-operative at 6 months and after 1, 3 and 5 years post-operative.If registration of Patient Reported Outcome Measures (PROM), which includes the EORTC-C30 and EORTC-BR23, are integrated in standard care at the Antoni van Leeuwenhoek, PROM data will be used to assess quality of life. cN0 patients with standard care (SLNB) will be asked to participate as control group.

Study burden and risks

Study participants will have the benefit of avoidance of axillary surgery and the complications associated with it (i.e. bleeding, wound infection, paresthesia, numbness, pain, lymphedema and arm movement impairment). The risk of a tumor-positive SLNB within the eligible patients is low (<3%). Moreover, previous studies indicate that omission of removal of axillary nodes in cN0 patients with a very low risk of tumor-positive SLNs after NST should not affect prognosis, as this is mainly determined by tumor biology. Study participants will be monitored yearly for disease recurrence up to 5 years, and will be asked to complete quality of life questionnaires at 5 points in time. It is estimated that completing the questionnaires will take 10 to 15 minutes at a time.

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 HER2-positive (Hormone receptor +/-) or triple negative breast cancer
• Primary tumor (T), clinical stage T1-3
• Neoadjuvant systemic therapy (NST), at least 3 cycles
• Tumor stage assessed with breast MRI before start NST
• Clinically node negative before start NST (no suspect axillary lymph nodes on ultrasound and
FGD-PET/CT, or negative cyto-/histopathology in case of suspect nodes)
• MRI after or during NST shows radiologic complete response
• Written and signed informed consent

Exclusion criteria

• Primary tumor (T) clinical stage T4
• Patients without ultrasound or FDG-PET/CT pre-NST
• History of breast cancer ipsilateral breast
• Synchronous contralateral breast cancer
• Synchronous metastatic disease

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	340
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-11-2019
Application type:	First submission
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
CCMO	NL70898.031.19