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# AXillary Surgery After NeoAdjuvant treatment:

## an international prospective multicenter cohort study of the EUBREAST study group to evaluate different surgical methods of axillary staging in clinically node-positive breast cancer patients treated with neoadjuvant chemotherapy

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## BACKGROUND

The optimal surgical staging of the axilla in breast cancer (BC) patients who convert from a clinically positive to a clinically negative node status (cN+ → ycN0, Fig. 1) through neoadjuvant chemotherapy (NACT) is still unclear. For many decades, axillary lymph node dissection (ALND) has been considered standard of care in this setting. However, ALND is associated with high morbidity and may therefore lead to reduced quality of life in BC patients (Fig. 2).

Various forms of axillary staging surgery after NACT are currently in use internationally with the aim to ensure oncological safety and to avoid over-therapy (ALND, TLNB, TAD, SLNB) [1]. The choice of the appropriate technique generally depends on the national and international recommendations and surgeon's preference. So far, no comparative data on the oncological outcome or the morbidity of the different procedures are available. Further research is needed to safely de-escalate the extent of axillary surgery in this patient group.

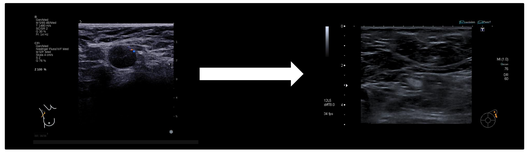


**Fig. 1.** Ultrasound image of a typical axillary lymph node metastasis prior to NACT (cN+; left) and unsuspicious lymph nodes after NACT (ycN0; right).

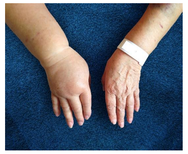


**Fig. 2.** Lymphedema of the right arm 12 years after ALND.

## REFERENCES

1. Banys-Paluchowski et al., Arch Gynecol Obster 2020, Axillary ultrasound for prediction of response to neoadjuvant therapy in the context of surgical strategies to axillary dissection…

## STUDY DESIGN (NCT04373655)

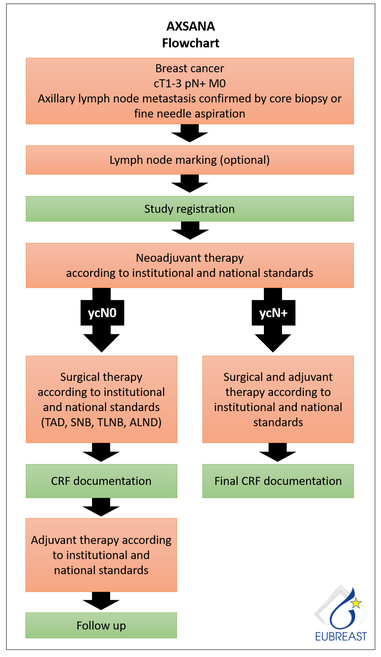
**Prospective multicenter cohort study**

**Target accrual:** 3000 pts.

**Study duration:** 5 years (enrollment) + 5 years (follow up)

**Primary endpoints**
- 5-year invasive disease-free survival
- 3-year axillary recurrence rate
- HRQOL (evaluated using 4 standardized questionnaires [EORTC QLQ-C 30, BR 23, Lymph ICF and SOC-13] at baseline and 1, 3, 5 years after surgery)

**Secondary endpoints** are the feasibility and performance of different axillary staging techniques (detection rate, number of removed lymph nodes and association with complications, arm morbidity and quality of life, operating time and use of clinical and economic resources); impact of learning curve, and the detailed mapping of surgical and oncological treatment standards in different countries.




## KEY ELIGIBILITY CRITERIA

**Inclusion criteria**
- Primary invasive breast cancer (confirmed by core biopsy)
- cN+ (confirmed by core biopsy or FNA)
- cT1-3
- Scheduled for NACT
- Female / male pts. ≥ 18 years old

**Exclusion criteria**
- Distant metastasis
- Recurrent or inflammatory BC
- Extramammary breast cancer
- Pregnancy
- < 4 cycles of NACT administered
- Pts. not suitable for surgical treatment

## CURRENT STATUS

**First patient recruited:** June 2020
**Current accrual (Oct 2020):** 70 pts.
**Open study sites:** 39

**Heads of National Steering Committees**

| | |
|---|---|
| Austria | Florentia Peintinger |
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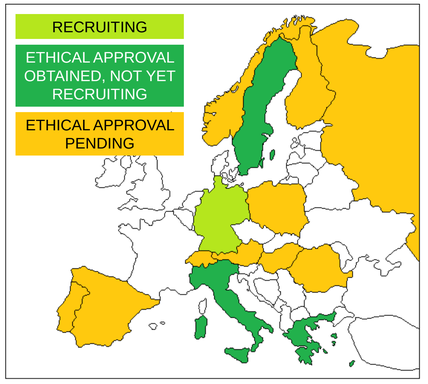


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