

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 (NCT 04373655)

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BACKGROUND

The optimal surgical staging procedure of the axilla in patients who convert from a clinically positive (cN+) to a clinically negative node status (ycN0) through neoadjuvant chemotherapy is still controversial. Widely diverse techniques such as full Axillary Lymph Node Dissection (ALND), Targeted Axillary Dissection (TAD), Targeted Lymph Node Biopsy (TLNB) and Sentinel Lymph Node Biopsy alone (SLNB) are given preference in different international guidelines. 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.

TRIAL DESIGN

Prospective multicenter cohort study

Target accrual: 3000 pts.

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

Primary endpoints

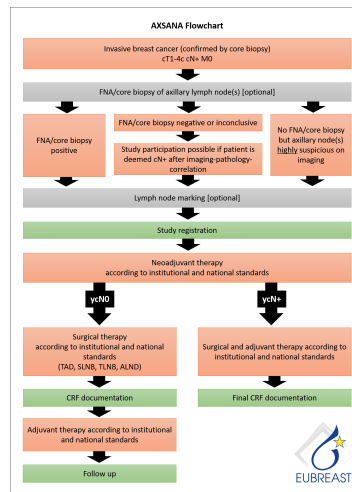
- 5-year invasive disease-free survival
- 3-year axillary recurrence rate
- HRQL [EORTC QLQ-C 30, BR 23, Lymph ICF and SOC-13] (baseline, year1,3,5)

Inclusion criteria

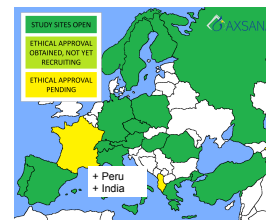
- Primary invasive breast cancer (confirmed by core biopsy)
- cN+ (confirmed by core biopsy or FNA)
- cT1-3
- Scheduled for NACT
- Female / male pts. ≥ 18 years old

Exclusion criteria

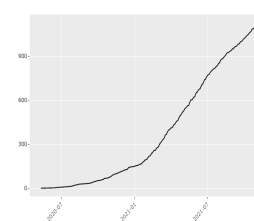
- Distant metastasis
- Recurrent or inflammatory BC
- Extramammary breast cancer
- Pregnancy
- < 4 cycles of NACT administered



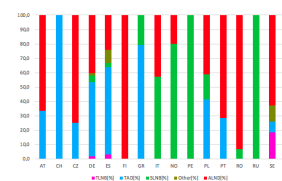
CURRENT STATUS



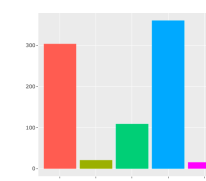
Patient recruitment (since June 2020)



Variability of Axillary Staging Techniques



Distribution of techniques - all patients



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Heads of National Steering Committees

Austria	Helikon Nina
Azerbaijan	Hajigat Valiyeva Qanimat
Czech Republic	Lukas Dostalek
Finland	Laura Niinikoski
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Russia	Petr Krivorotko
Spain	Isabel Rubio
Sweden	Jana de Boniface
Switzerland	Maria Luisa Gasparri
Turkey	Guideniz Karadeniz Cakmak

First patient recruited: June 2020
Current accrual (Nov 2021): 1177 pts.
Open study sites: 190
Participating countries: 21

100% of datasets are monitored for plausibility (remote monitoring).

For more information visit axsana.eubreast.com

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