

Wie viel Operation der Axilla braucht es bei cN+? -Ergebnisse der AXSANA sowie Update EUBREAST/TAXIS

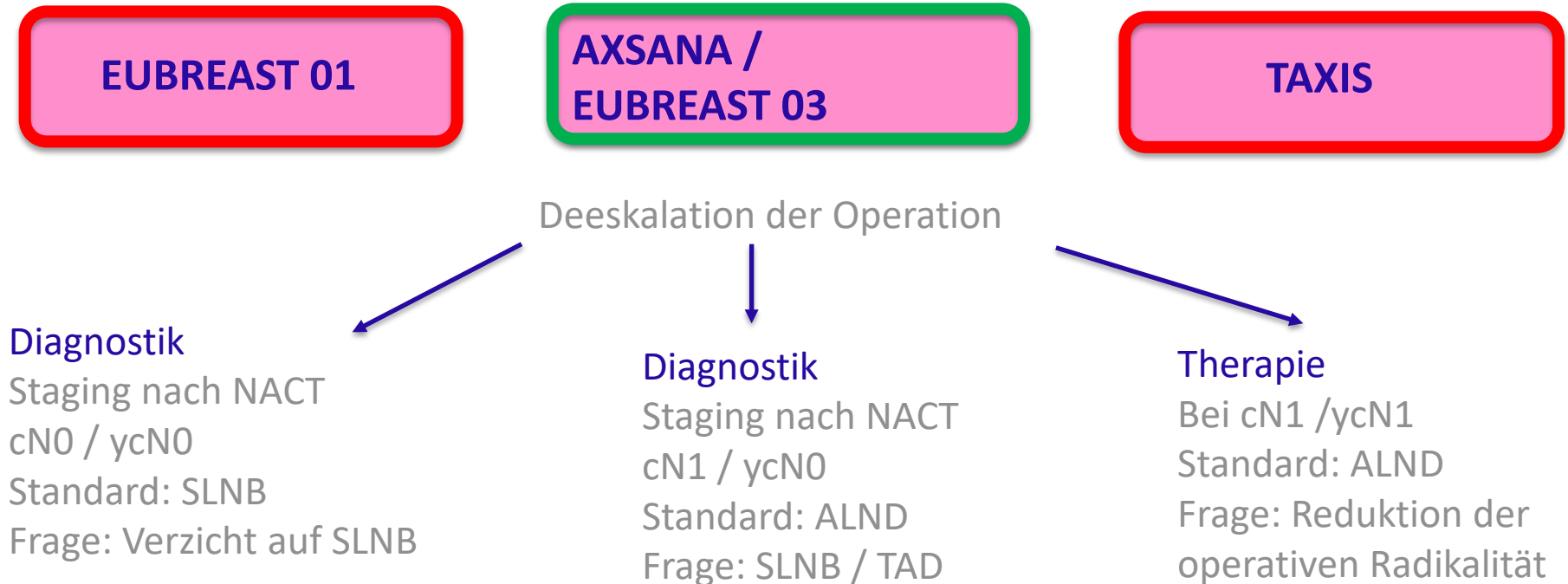
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GBG – Studien operatives Subboard

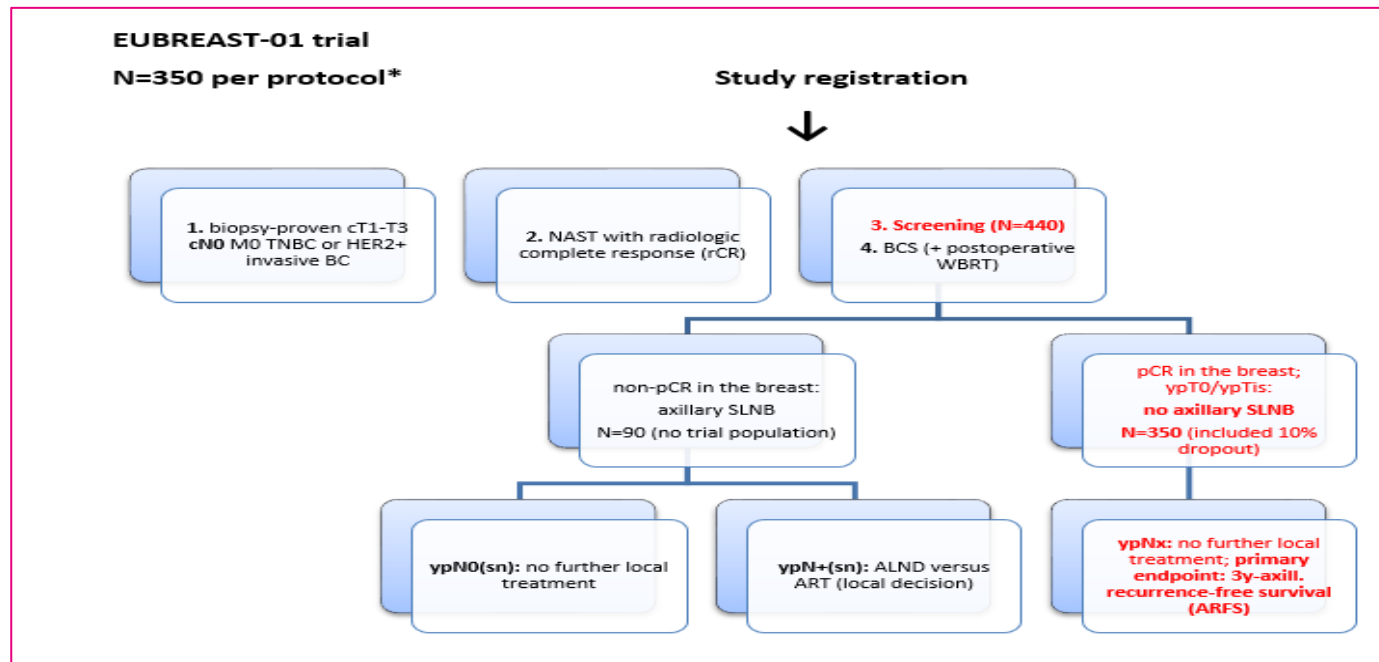


Rationale für die EUBREAST 1 Studie

Tab.: List of trials with axillary interventions after NAST reporting outcomes regarding ypN+ rate with respect to initial cN status and breast pCR.

Study for ypN+ rate in cN0 patients with breast pCR (N) after NAST	ER+/ HER2-	HER2+	TNBC
Barron [2018] N=5,377	n.d.	1.6%	1.6%
Samiei [2018] N=986	6.7%	ER+/HER2+: 1.6% ER-/HER2+: 0%	1.5%
Tadros [2017] N=116	n.d.	0%	0%
Van der Noordaa [2020] N=89	0%	0%	0%

EUBREAST 1 / ASLAN / ASICS



EUBREAST 01 – Stand Nov 2025

	Screened	pCR (%)
Target	440	350 (80%)
Completed	388	310* (80%)



$$310 / 350 = 89\%$$

*Estimated, 7 pCR are missing

Follow-up information in women with pCR

381 patients



309 patients

Median follow-up: 24 months (range 1-54)

Median follow-up expected by the time of analysis (Q1 2028): 60 months (range 36-84)

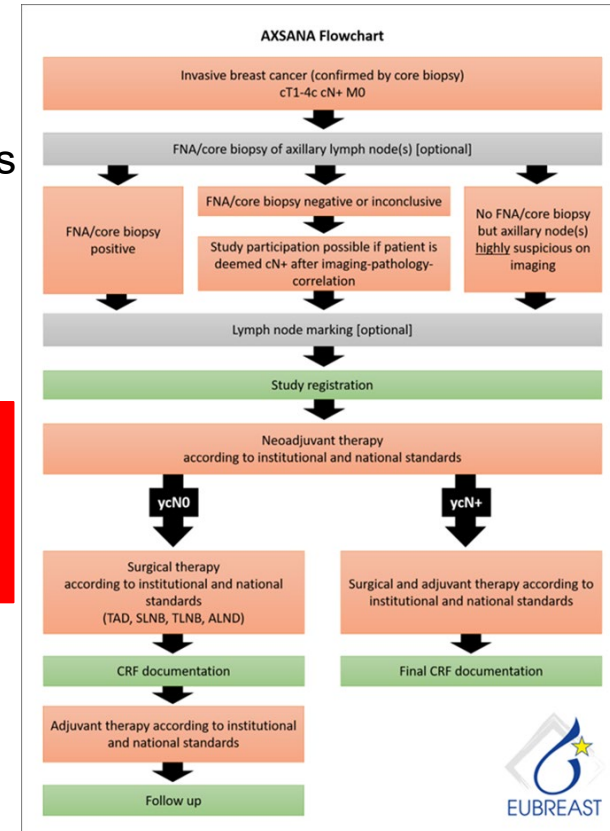
AXSANA Study

- Ongoing, international, multicentric, non-interventional prospective registry
- In cN+ (cN1-3a) → ycN0 different surgical staging procedures are allowed according to the physician's choice (ALND/SLNB/TAD/TLNB)
- (Neo-) Adjuvant systemic and locoregional treatment according to institutional and national guidelines

Co-primary endpoints

- Axillary recurrence-free survival
- Invasive breast cancer-specific disease-free survival
- QoL and arm morbidity

**7215
Patient*innen**



More versus less invasive axillary surgical staging procedures in breast cancer patients converting from a clinically node-positive to a clinically node-negative stage through neoadjuvant chemotherapy - primary endpoint analysis of the international prospective multicenter AXSANA/EUBREAST 3(R) study

Kühn T^{1,2}, Banys-Paluchowski M, Ditsch N, Stickeler E, Hauptmann M, Schroth J, Karadeniz Cakmak G, Hahn M, Thill M, Reimer T, Fröhlich S, Schmidt E, Lux MP, Kolberg HC, Rubio IT, Gasparri ML, Kontos M, Bonci EA, Niinikoski L, Murawa D, Pinto D, Peintinger F, Schlichting E, Nina H, Valiyeva Qanimat H, Vanhoeij M, Rebaza L, Aktas Sezen B, Jursik K, Kadayaprath G, Dostalek L, Kothari A, Perhavec A, Ivanov T, Zippel D, Thongvitokomarn S, Adamczyk B, Gurleyik MG, Watermann D, Porpiglia M, Grasshoff ST, Loibl S, Krug D, Lebeau A, Di Micco R, Gentilini OD, de Boniface J, Hartmann S and the AXSANA Study Group

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Axillary dissection for low-volume nodal involvement after neoadjuvant chemotherapy in node-positive patients: the AXSANA trial

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Breast Cancer Research and Treatment

<https://doi.org/10.1007/s10549-025-07635-4>

RESEARCH

Radar reflectors for node-positive patients after neoadjuvant chemotherapy for breast cancer—a (EUBREAST-03) trial

Maggie Banys-Paluchowski · St Oreste Davide Gentilini, et al. 



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European Journal of Cancer



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journal homepage: www.ejso.com



Lost axillary markers after neoadjuvant chemotherapy in breast cancer patients - data from the prospective international AXSANA (EUBREAST 3)

Original Reports | Breast Cancer

Marking Techniques for Target Lymph Nodes in Node-Positive Breast Cancer Treated With Neoadjuvant Therapy in the AXSANA/EUBREAST-03/AGO-B-053 Study

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Performance of AUS after NACT by tumor subtype

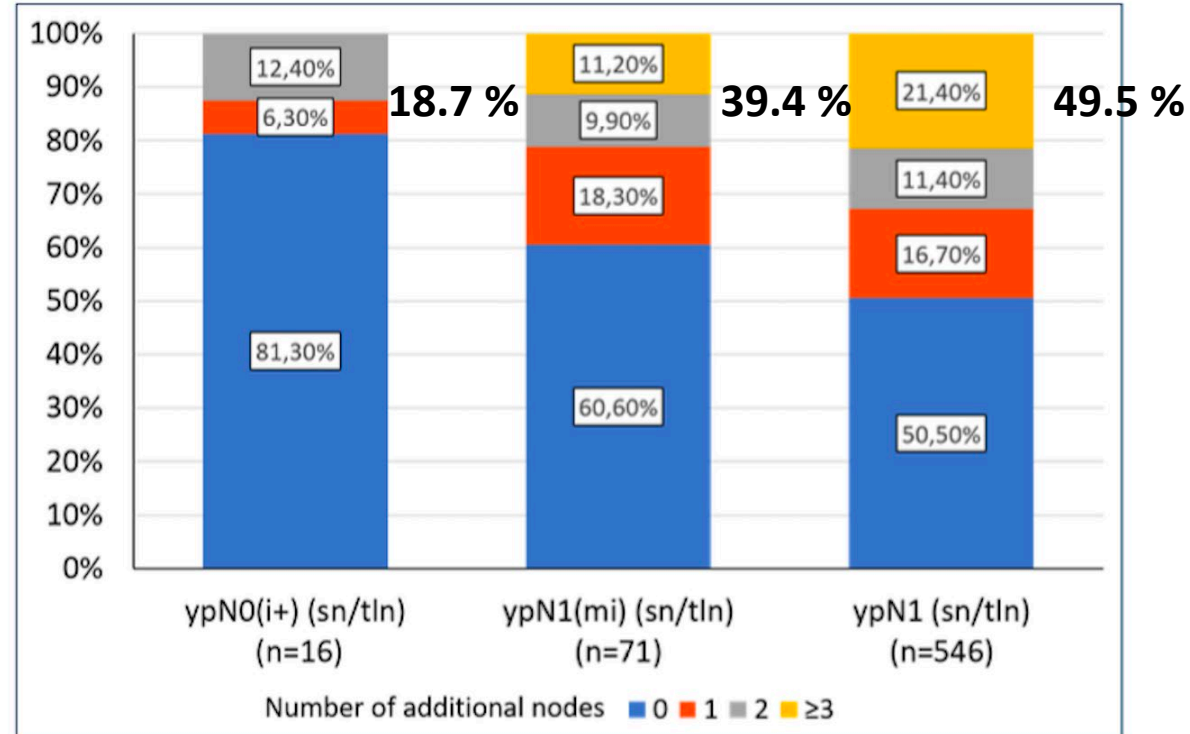
Analysis	Overall (n=3260)	HR+/HER2- (n=1487)	HR+/HER2+ (n=754)	HR-/HER2+ (n=390)	HR-/HER2- (n=629)	P-value*
Sensitivity (%)	46.4	46.2	43.9	37.5	52.9	0.14
Specificity (%)	78.9	78.4	77.6	79.3	80.5	0.71
PPV (%)	64.2	81.9	43.7	23.3	53.5	<0.001
NPV (%)	64.3	40.8	77.7	88.3	80.6	<0.001

*chi-square test

Hartmann SABCS 2024 Di Micco et al 2025

Non – SLN involvement bei ypN0(i+) / ypN1 (mi) / ypN1 (SLN/TAD)

Figure 2: Frequency of additional metastatic non sentinel / non target lymph nodes by cALND



Upgrade of N- Stage in ypN0(i+) / ypN1 (mi) (sn/tad)

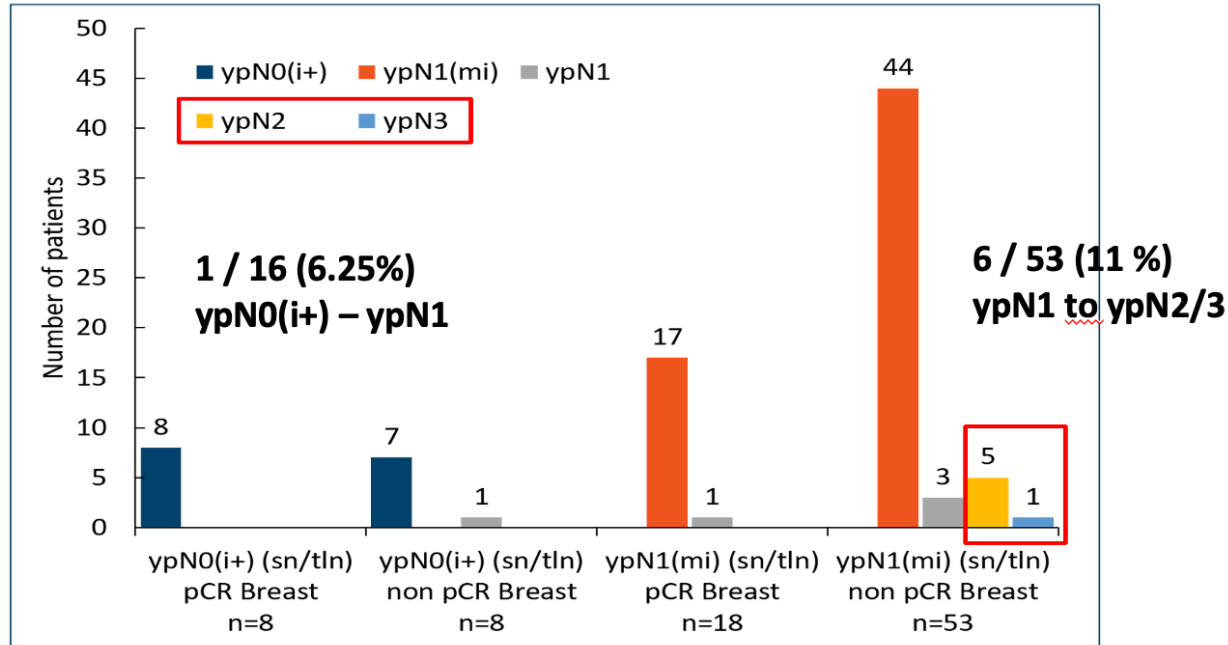


Figure 5: Upgrade of N-stage by cALND for patients with ypN0(i+) (sn/tln) and ypN1(mi) (sn/tln) related to tumor response in the breast

Therapieänderung durch ALND in ypN0 (i+) und ypN1(mi)

ypN-stage	Treatment Modification		No Treatment Modification
ypN1(mi) (sln/tln) n = 71	Die komplettierende ALND bringt keinen diagnostischen Erkenntnisgewinn bei ypN0(i+) / ypN1(mi) (sln/tad)		
			70

Marking Techniques for Target Lymph Nodes in Node-Positive Breast Cancer Treated With Neoadjuvant Therapy in the AXSANA/EUBREAST-03/AGO-B-053 Study

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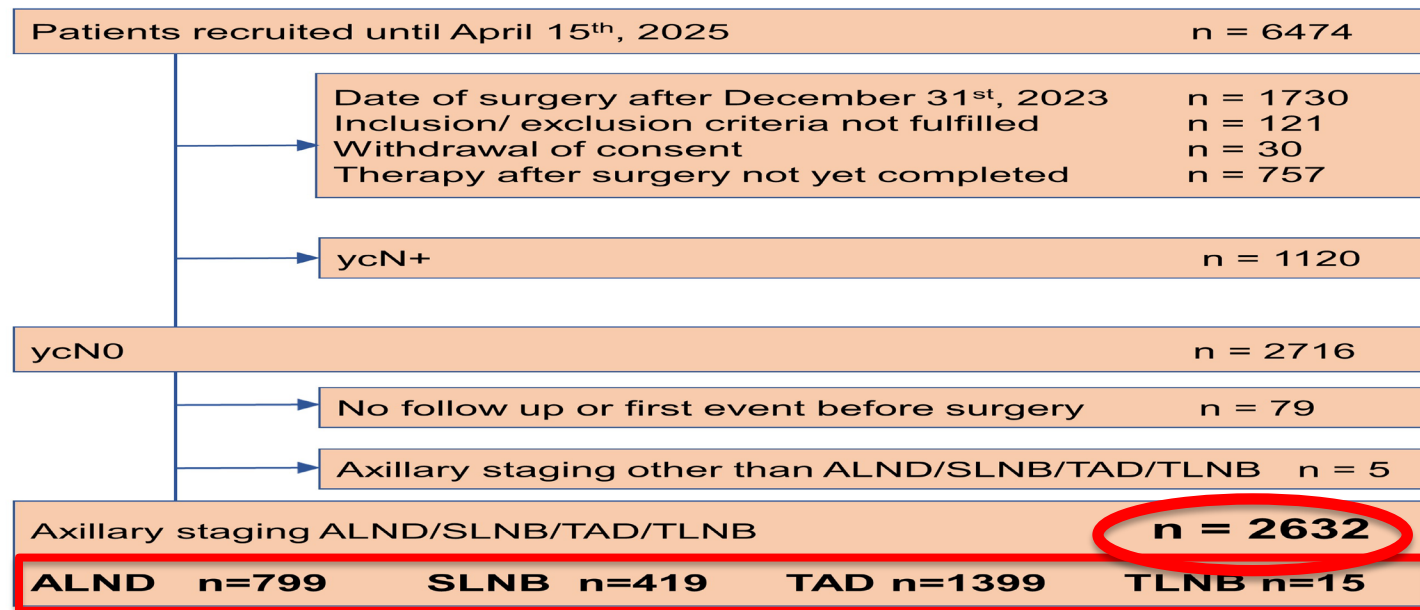
Marking technique pre-NACT	Number of pts.	Number of removed nodes during	
		TAD/TLNB	TLN detection rate
		Mean ± SD	
Clip	1,594	2.95 ± 1.90	89.6%
Carbon ink	118	2.99 ± 1.73	94.9%
Total probe-guided detection markers	355	2.81 ± 1.73	96.6%
Magnetic seed	225	2.77 ± 1.64	96.9%
Radar marker	102	3.10 ± 2.01	96.1%
Radioactive seed	16	1.88 ± 0.72	100%
RFID	10	2.40 ± 1.08	90%
Other	2	2.00 ± 0.00	100%
Combination	33	2.76 ± 1.42	93.9%
Total	2,100	2.92 ± 1.86	91.2%

2.500 pts with TAD

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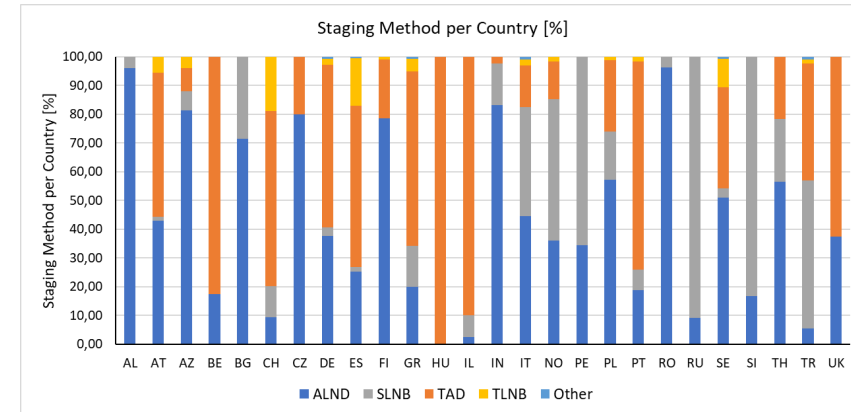
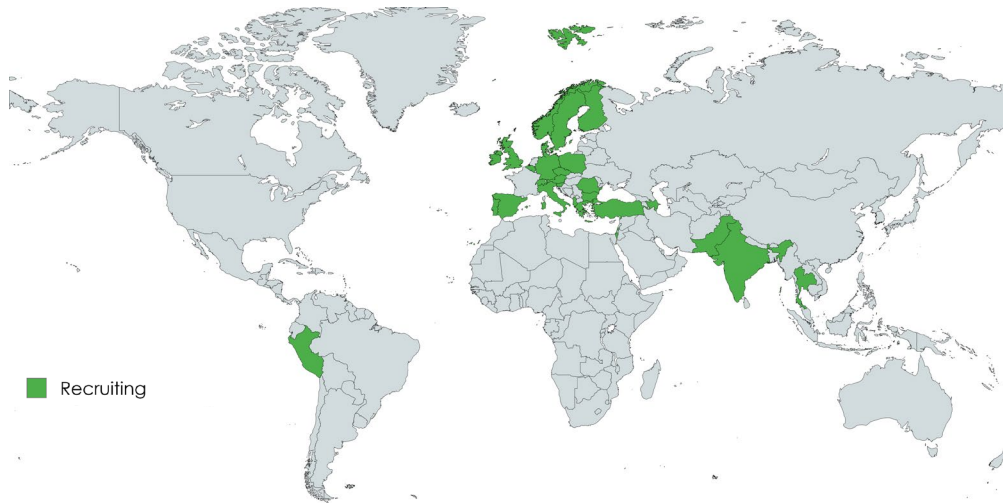
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Consort Diagramm

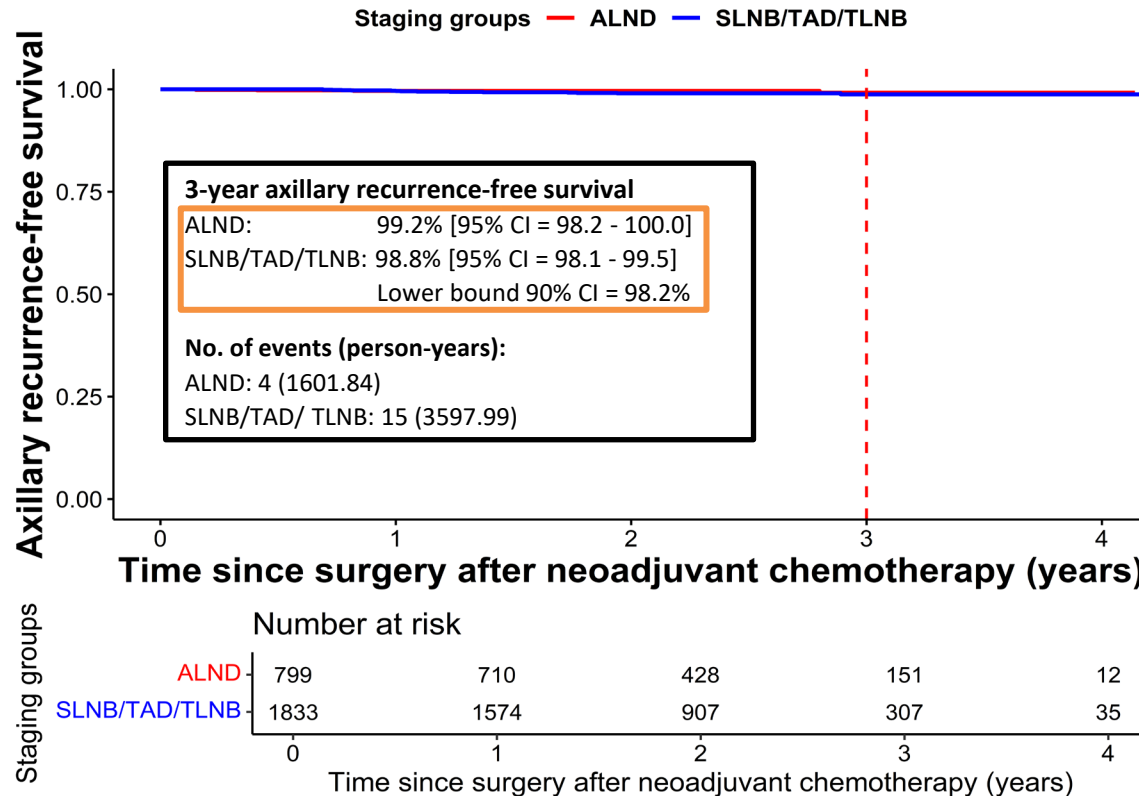


Trial status

- The trial includes patients from 288 study sites
- 26 countries
- Recruitment started in 2020



ALND vs SLNB/TAD/TLNB (3-year axillary recurrence-free survival)



Patient characteristics ALND vs SLNB/TAD/TLNB

Characteristic	Overall (n/%) (n = 2632)	ALND (n/%) (n = 799)	SLNB/TAD/TLNB (n/%) (n = 1833)	p-value
Clinical tumor stage at diagnosis				
cT1	580 (22.0)	131 (16.4)	449 (24.5)	<0.001
cT2	1670 (63.4)	497 (62.2)	1173 (64.0)	
cT3	317 (12.0)	127 (15.9)	190 (10.4)	
cT4	65 (2.5)	44 (5.5)	21 (1.1)	
Number of suspicious nodes				
1-3	2138 (81.8)	501 (63.4)	1637 (89.7)	<0.001
≥ 4	476 (18.2)	289 (36.6)	187 (10.3)	
Median size of the largest suspicious node, mm (IQR)	17 (10)	18 (12)	16 (9)	<0.001
Type of breast surgery				
BCS	1732 (66.4)	427 (54.3)	1305 (71.6)	<0.001
Mastectomy	876 (33.6)	359 (45.7)	517 (28.4)	
Axillary Radiotherapy				
Yes	1406 (56.5)	403 (53.0)	1003 (58.0)	0.024
No	1084 (43.5)	357 (47.0)	727 (42.0)	
Nodal Stage after NACT				
ypN0	1648 (62.6)	524 (65.6)	1124 (61.4)	0.044
ypN+	983 (37.4)	275 (34.4)	708 (38.6)	

No significant differences

- Median age
- Tumor subtype, histological type, grading
- Breast pCR
- CHT regimen, breast/chest wall radiotherapy and adjuvant systemic therapy

3-year recurrences all endpoints (ALND vs SLNB/TAD/TLNB) univariate and multivariate cox regression

Endpoint (ALND vs. SLNB/TAD/TLNB)	HR [95 % CI]	aHR [95 % CI]*
Invasive breast cancer-free survival	1.30 [0.99, 1.71]	1.03 [0.76, 1.38]
Axillary recurrence-free survival	0.61 [0.19, 2.03]	0.54 [0.15, 1.90]
Regional recurrence	0.58 [0.21, 1.65]	0.52 [0.16, 1.66]
Local recurrence	1.06 [0.55, 2.06]	1.19 [0.60, 2.36]
Locoregional recurrence	0.83 [0.46, 1.50]	0.93 [0.51, 1.70]
Overall survival	1.35 [0.89, 2.04]	1.04 [0.66, 1.64]
Distant recurrence	1.41 [1.05, 1.90]	1.03 [0.74, 1.44]

* Adjusted for significant categories in univariate analysis

SLNB vs TAD (3-year axillary recurrence-free survival)

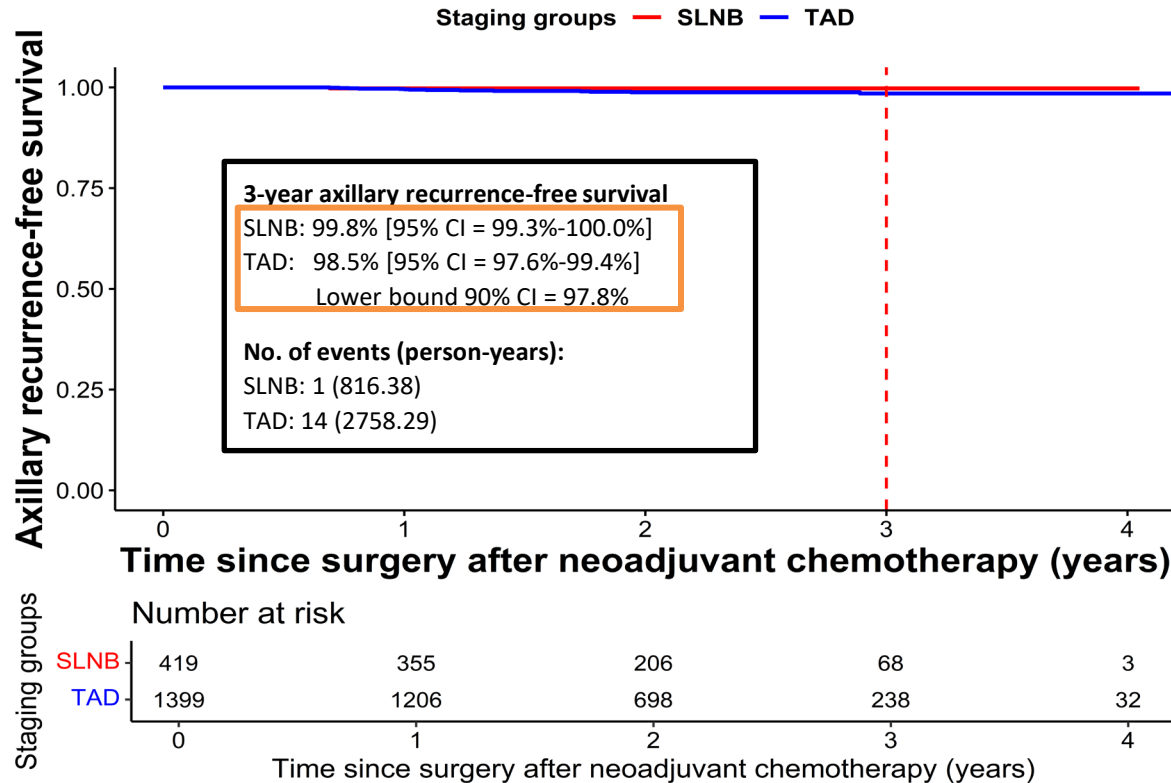
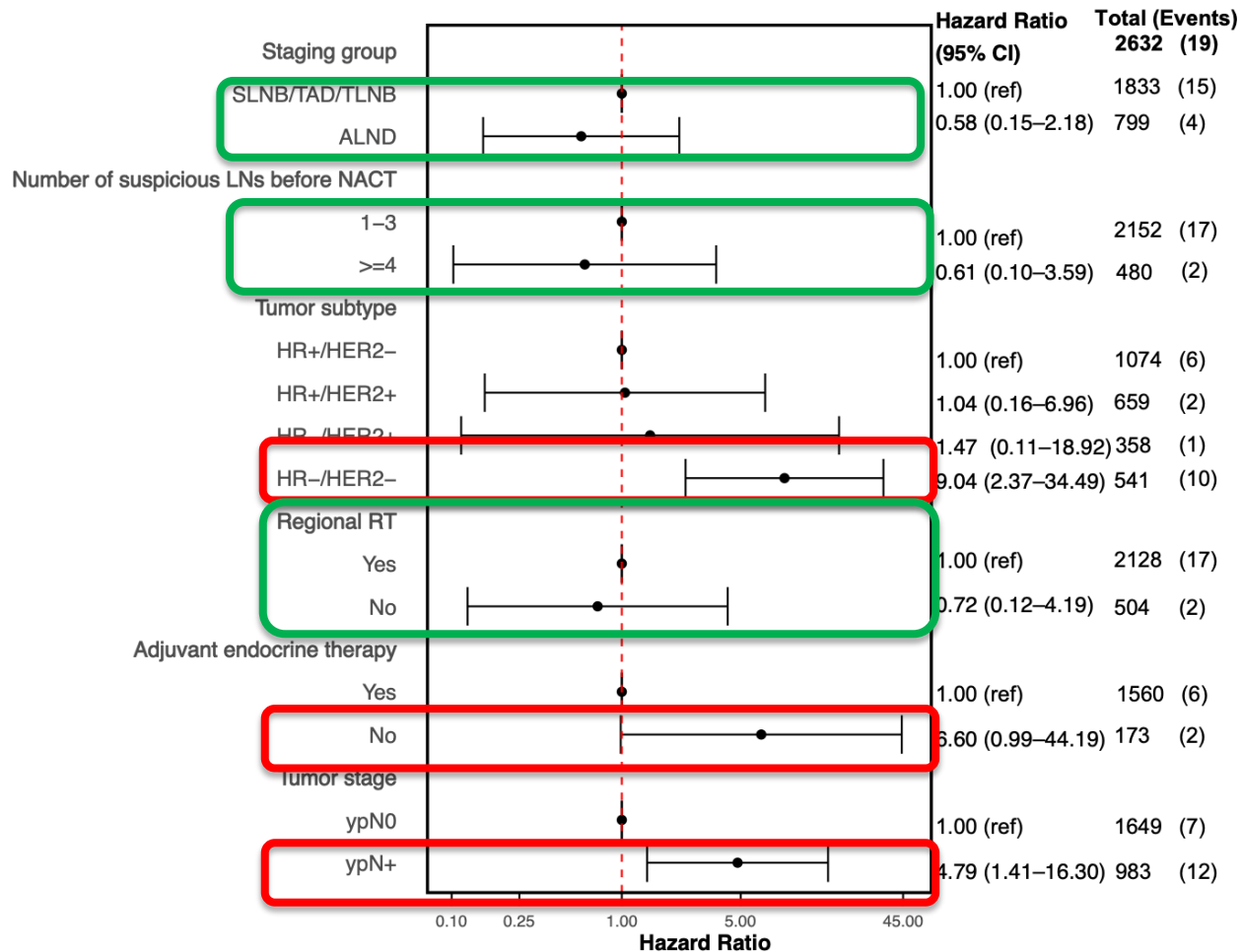
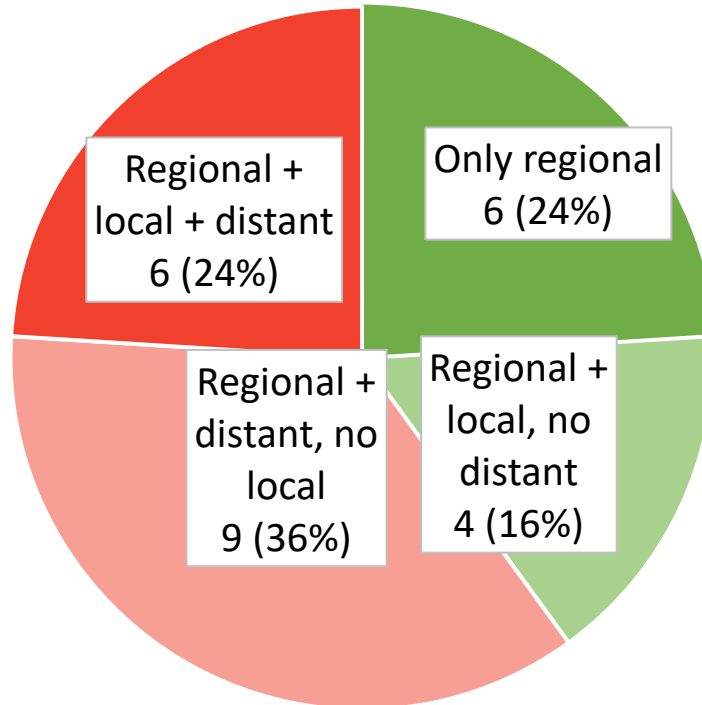


Figure 4: Forest plot of multivariable hazard ratios for ARFS in patients with planned axillary staging ALND or less invasive SLNB/TAD/TLNB after neoadjuvant chemotherapy



Association of axillary and other relapses (25 / 2632)



Conclusion

Sowohl SLNB als auch TAD sind in Bezug auf die regionäre Kontrolle sicher

Ein höheres initiales Tumorstadium überträgt sich nicht in eine erhöhte Rezidivrate

Sind SLNB und TAD gleichwertig ?

- Höhere Detektionsrate für TAD vs SLNB (weniger ALND aus diagnostischen Gründen)
- Weniger LK bei TAD (Median 3) als bei SLNB (Median 4)
- Höhere diagnostische Genauigkeit (FNR) für TAD vs SLNB





ORIGINAL ARTICLE – BREAST ONCOLOGY

Oncologic Outcomes of Sentinel Lymph Node Biopsy Versus Targeted Axillary Dissection for Node-Positive Breast Cancer Patients After Neoadjuvant Chemotherapy: A Systematic Review and Meta-Analysis

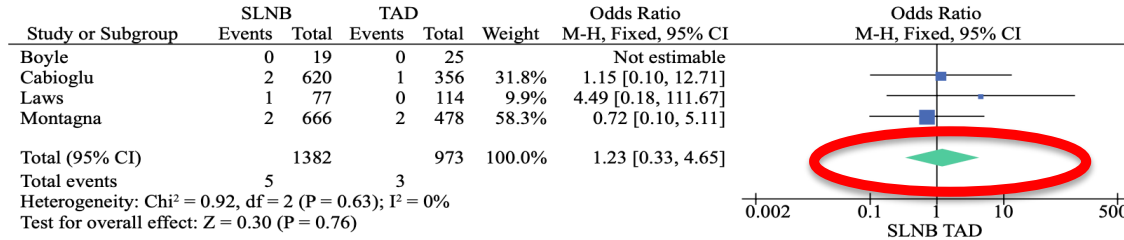


FIG. 2 Forest plot showing pooled estimate of axillary recurrences for patients undergoing sentinel lymph node biopsy (SLNB) versus targeted axillary dissection (TAD)

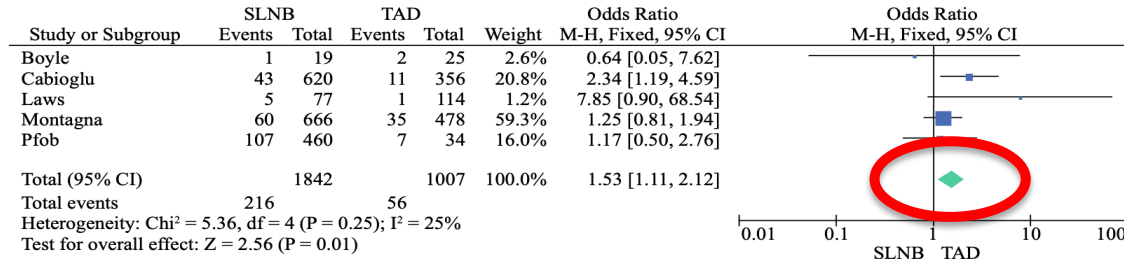


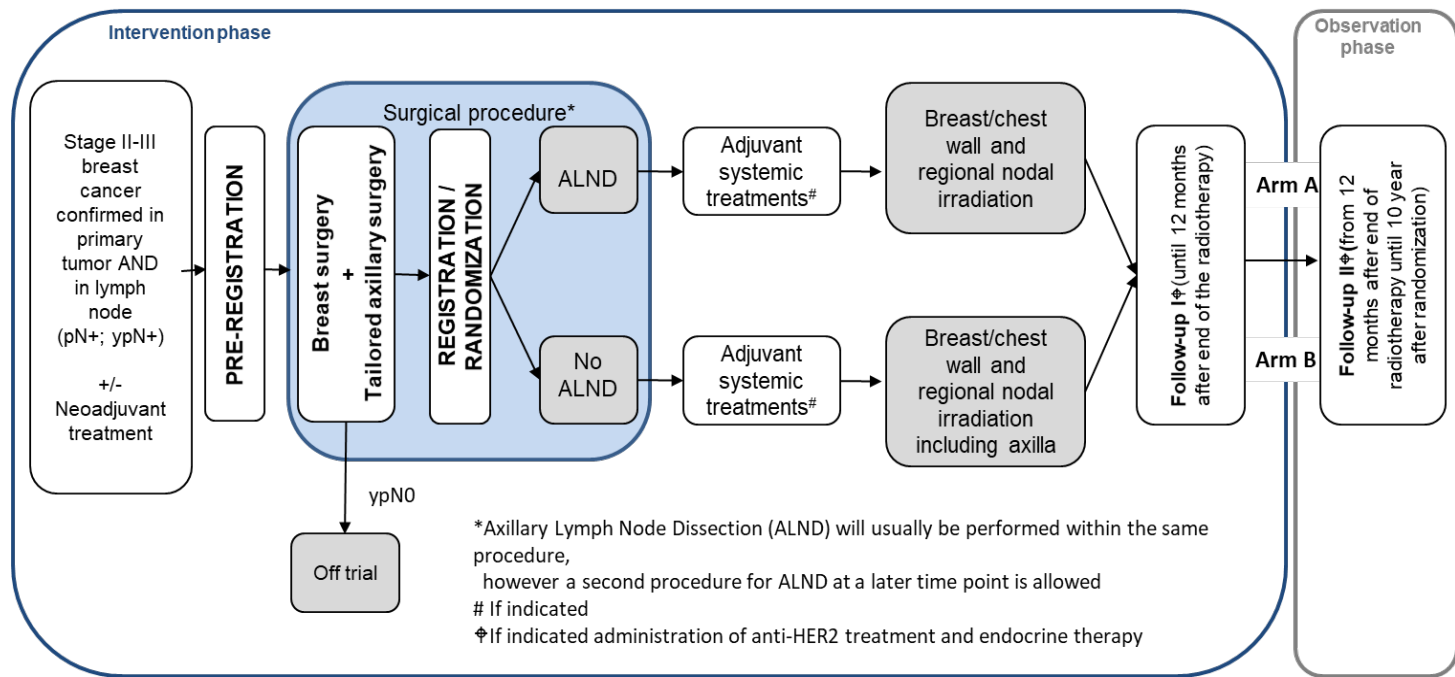
FIG. 3 Forest plot comparing disease-free survival between sentinel lymph node biopsy (SLNB) and targeted axillary dissection (TAD) cohorts

- Bitte Nehmen Sie am Data Clearing teil und übermitteln Follow-UP Daten
- Amendment: Alle N-Stadien erlaubt



THANK YOU

TAXIS – Trial Design



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