



Update

Aktuelle Standards der lokoregionären Therapie des Mammakarzinoms 2024

Conflict of Interest

- leer

- **Rückblick Vortrag 2023**
- **Themen und Studienergebnisse 2023, hierin:**
 - Operative Studien der GBG 2023
 - Ausblick 2024

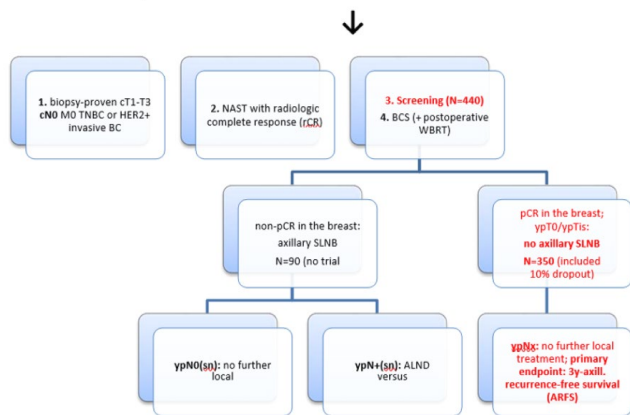
- **Operatives Axilläres Management nach Neoadjuvanz**
 - EUBREAST-01 / **UPDATE 2024**
 - OPBC-04/EUBREAST-06/OMA study
 - OPBC-05/EUBREAST-14R/ICARO study / **UPDATE 2024**
- **Interdisziplinäres axilläres Management bei (y)cN+**
 - TAXIS (OPBC-03, SAKK 23/16, IBCSG 57-18, ABCSG-53, GBG 101) / **UPDATE 2024**
- **Radioonkologische De-escalation**
 - Hypofraktionierung Lymphabfluss
 - Hypofraktionierung mit simultan integriertem Boost (SIB)

- Axilläre Operationen nach NACT: EUBREAST-01, iCARO
- Sentinel node Biopsy EBC: SOUND
- Axilläres interdisziplinäres Management: TAXIS
- Strahlentherapie nach NACT: NSABP B51
- Strahlentherapie nach Brustreterhaltung: LUMINA / PROSPECT / IDEA

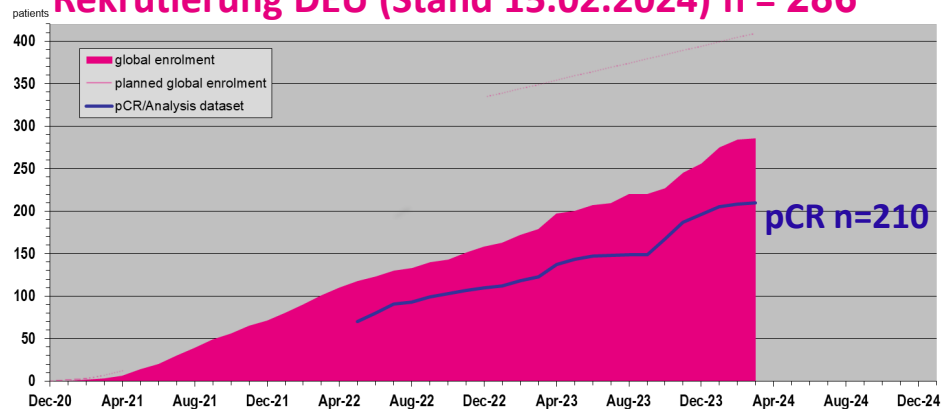
EUBREAST-01 (GBG 104)

N= 350 per protocol

Study registration



Rekrutierung DEU (Stand 15.02.2024) n = 286



Top-Rekrutierer :



| Zentrum | Hauptprüfer/in | Patienten pro Zentrum |
|-------------------------------------|----------------------------|-----------------------|
| Klinikum Südstadt Rostock | PD Dr. Angrit Stachs | 58 |
| Carl-Thiem-Klinikum Cottbus | Dr. Nikola Bangemann | 22 |
| Franziskus-Hospital Harderberg | Dr. Elisabeth Thiemann | 22 |
| DRK Kliniken Berlin Köpenick | Dr. Anke Kleine-Tebbe | 22 |
| Universitätsklinikum Essen | Prof.. Oliver Hoffmann | 17 |
| St. Josefs-Hospital Wiesbaden | Dr. Carolin Hammerle | 15 |
| Klinikum Worms | Dr. Antje Nixdorf | 10 |
| Johanniter-Krankenhaus Stendal | Dr. Andrea Stefek | 10 |
| Albertinen Krankenhaus Hamburg | Dr. Uwe Herwig | 9 |
| Sana Kliniken Leipziger Land, Borna | Dipl. med. Henning Eichler | 9 |
| Universitätsklinikum Heidelberg | Prof. Dr. Jörg Heil | 7 |
| Klinikum Kassel | Lydia Dautzenberg | 7 |

Are nodal isolated tumor cells (ITCs) after neoadjuvant chemotherapy an indication for axillary dissection?

- 412 patients treated with NAC followed by surgery from 01/2009-05/2022.
- cT1-4 cN0-3
- 146 (35.4%) had completion ALND and 266 (64.6%) did not.
- Median patient age was 48 years.
- 68% had biopsy-proven N1 disease.
- In the ALND group, additional positive nodes were found in 43/146 (29.5%) of cases, and consisted of macrometastases in 11/146 (7.5%), micrometastases in 9/146 (6.2%), and ITCs in 23/146 (15.8%).
- 5-year rates of any AR, LRR, and any invasive recurrence in the entire cohort were 2.7% (95% CI 1.2-5.4), 2.8% (95% CI 1.2-5.4) and 16% (95% CI 11-21), respectively.
- no statistical difference between patients who underwent ALND and those who did not in any of the 3 endpoints (2.2% v 3.1%, p=0.6), (2.6% v 3.0%, p=0.4) and (14% v 18%, p=0.12), respectively.

Presenting/Contact Author(s)



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Omission of sentinel node biopsy in early breast cancer



18TH ST.GALLEN INTERNATIONAL BREAST CANCER CONFERENCE 2023
15 – 18 March 2023, Vienna/Austria

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SGBCC 2023

Omission of sentinel node biopsy in early breast cancer

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Chairman of EUBREAST ETS

Oreste D. Gentilini-SGBCC 2023

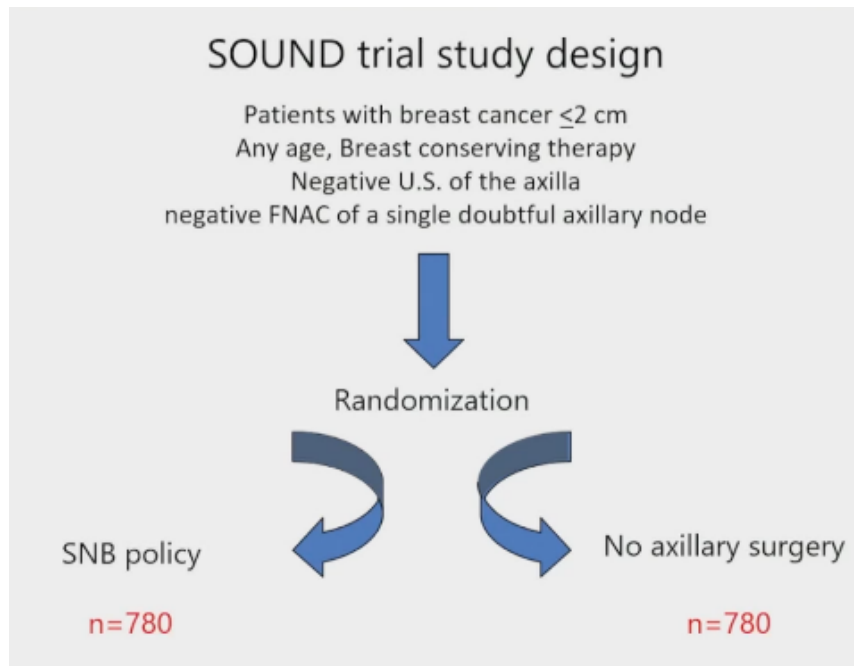
Oreste Gentilini

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SGBCC 2023

Omission of surgical staging of the axilla

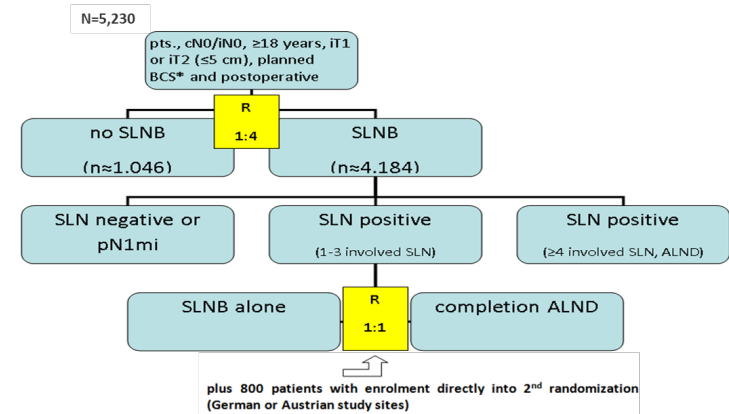
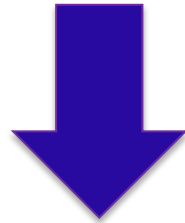
Omission of sentinel node biopsy in early breast cancer



5y-DDFS
97,7% in SLNB arm
98,0% in the no axillary surgery arm
Log-rank-test $P=0.665$; HR 0,84; 90%CI 0.45-1.54; non-inferiority $P=0.023$

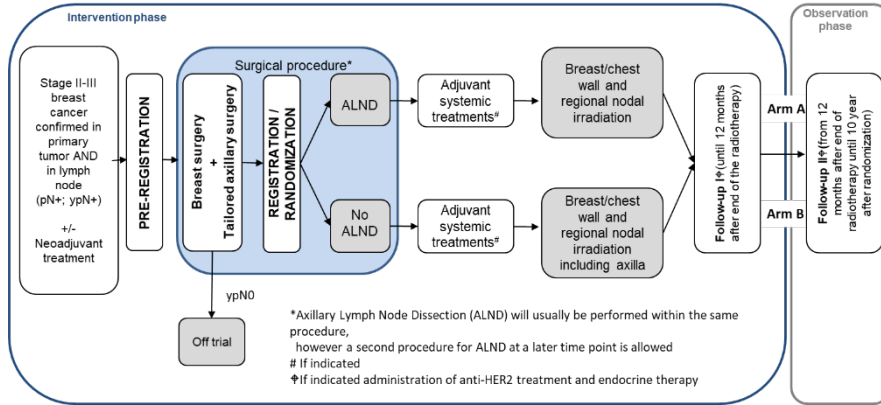
INSEMA (GBG 75) AUSBLICK

- Follow-Up Phase bis Oktober 2024 → Einschluss in das GBG-Selbstaufkunftsregister (PSA) vor der Abschlussvisite möglich
- **Auswertung primärer Endpunkt Q3 2024**
- **Late-Breaking Abstract SABSC 2024 geplant**

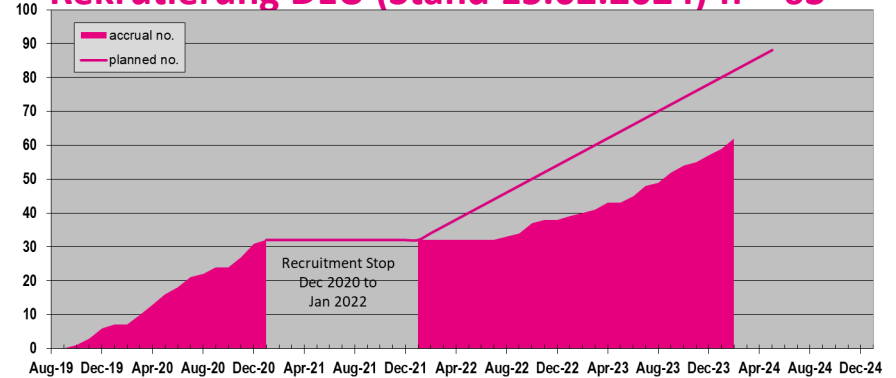


**Aktuelles Follow-Up erheben, Dokumentation und
Queries abschliessen!**

TAXIS (GBG 101)



Rekrutierung DEU (Stand 15.02.2024) n = 63



Top-Rekrutierer seit erneuten Start:

| Zentrum | Hauptprüfer/in | Patienten pro Zentrum |
|--|----------------------------|-----------------------|
| Universitätsklinikum Wuppertal | Prof. Vesna Bjelic-Radicic | 17 |
| Franziskus-Hospital Harderberg | Dr. Elisabeth Thiemann | 8 |
| Universitätsklinikum Heidelberg | Prof. Jörg Heil | 4 |
| ViDia Christliche Kliniken Karlsruhe, Diakonissenkrankenhaus | Dr. Sibylle Perez | 1 |
| Evang. Kliniken Essen-Mitte (KEM) | PD Dr. Mattea Reinisch | 1 |

Subprojekt: Association of Axillary Dissection With Systemic Therapy in Patients With Clinically Node-Positive Breast Cancer

487 female patients, out of 44
unit, 6 countries

no observed association of ALND
with the proportion of patients
undergoing postneoadjuvant
systemic therapy, type of
postneoadjuvant chemotherapy or
endocrine therapy

Table 2. Number of Lymph Nodes Removed by Type of Surgery

| No. of lymph nodes removed | Type of surgery | | Difference (95% CI) ^a |
|--|-----------------------|--------------------------|----------------------------------|
| | Arm A: ALND (n = 250) | Arm B: no ALND (n = 250) | |
| Overall, median (IQR) | | | |
| Total | 18 (13-24) | 5 (3-7) | 12 (11-13) |
| Positive | 4 (2-8) | 2 (1-4) | 1 (1-2) |
| Negative | 12 (8-16) | 2 (1-4) | 9 (8-10) |
| Upfront surgery setting: HR+/ERBB2-, median (IQR) | | | |
| Total No. | 151 | 145 | NA |
| Total | 19 (14-26) | 5 (4-8) | 14 (12-15) |
| Positive | 4 (2-9) | 3 (1-4) | 2 (1-2) |
| Negative | 12 (9-18) | 2 (1-4) | 10 (9-11) |
| Neoadjuvant chemotherapy, ^b median (IQR) | | | |
| Total No. | 77 | 74 | NA |
| Total | 15 (12-19) | 4 (3-7) | 10 (9-12) |
| Positive | 2 (1-5) | 2 (1-3) | 1 (0-1) |
| Negative | 12 (7-15) | 2 (1-4) | 9 (7-11) |

Strahlentherapie bei cN+ → ypN0 nach NACT

Prospective, superiority randomized controlled trial, 1641 pts., 2013-2020, median follow-up 59.5 months
cT1-3 cN1 (FNA/CNB) → ypN0 (SLNB/ALND) after standard neoadjuvant chemotherapy

Randomization:

- BCS: RT breast vs. RT breast + regional nodal irradiation
- Mastectomy: No RT vs. Post-mastectomy RT + regional nodal irradiation

Primary endpoint: Invasive breast cancer recurrence-free interval

80% power to detect 4.6% absolute reduction (HR 0.65)

Results:

No improvement in

- BCRFI (HR 0.88),
- isolated locoregional recurrence-free interval (HR 0.37)
- distant recurrence-free interval (HR 1.00), DFS (1.06) and
- OS (HR 1.12)

CAVE:

- **Kurzes Follow-up**
- **cT3 unterrepräsentiert**

Strahlentherapie nach BEO

| Trial | N | Time-frame | Inclusion criteria | Follow up | Local recurrence (95%-CI) |
|------------------------|-----|------------|--|-----------|--------------------------------|
| LUMINA (NEJM 2023) | 500 | 2013-2017 | ≥ 55 years, pT1 pN0 R0 (≥1 mm) ER ≥1% PR ≥20% HER2 neg. Ki67 ≤ 13.25% (central lab) | 5 y | 2.3% (1.2-4.1%) |
| IDEA (SABCS 2023) | 200 | 2015-2018 | 50-69 years, pT1 pN0 R0 (≥2 mm) ER/PR pos. HER2 neg., Oncotype Dx RS ≤ 18 | 5 y | 50-59 y. 3.3% 60-69 y. 3.6% |
| PROSPECT (Lancet 2023) | 201 | 2011-2019 | ≥50 years, unifocal cT1 cN0, no LVI, no EIC, R0 (≥2 mm), ER/PR pos. and/or HER2- pos., preoperative breast MRI | 5 y | 1.0% (-5.4%) |

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und Partnerschaft – führend in der
Brustkrebs-Forschung

