EUBREAST

AXSANA

# AXillary Surgery After NeoAdjuvant Treatment

-EUBREAST 3-
NCT 04373655

A prospective multicenter cohort study to evaluate different surgical methods of axillary staging (sentinel lymph node biopsy, targeted axillary dissection, axillary dissection) in clinically node-positive breast cancer patients treated with neoadjuvant chemotherapy

## Frequently Asked Questions (FAQ)

| Date | Question | Answer |
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| 28.09.2020 | When should we enroll the patients? Before neoadjuvant therapy or before surgery? In the protocol, one of the exclusion criteria is “Less than 4 cycles of NACT administered” | We encourage study sites to enroll patients before NACT, because at this time all the necessary data like the exact type of the marker (in case of lymph node marking) and imaging results are known. However, you can enroll patients until the day of surgery if you can provide all data required by the eCRF. In that case, do not enroll patients who discontinued NACT and received less than 4 cycles.<br><br>Keep in mind that patients need to complete baseline QoL questionnaires within 4 weeks before the surgery (i.e. between 4 weeks before surgery and the day of surgery). |
| 18.02.2021 | Is it really necessary to confirm lymph node metastasis by FNA/core biopsy? | No.<br><br>Since the amendment in October 2020, it is possible to enroll all cN+ patients. In case a minimally invasive biopsy (core biopsy or FNA) was conducted and the result is negative or inconclusive, patients can be enrolled if you still consider them cN+. We recommend discussing these cases in a multidisciplinary tumor board to decide whether they should be considered cN+ or cN0. |
| 9.10.2020 | We routinely mark lymph nodes with MagSeed. It is a kind of a magnetic clip. Should we click both “Magnetic seed” and “Clip”? | No. You should choose “Clip” only if you used a non-magnetic not-radioactive clip. In case of MagSeed please chose “magnetic seed”.<br><br>Of course, if you inserted both MagSeed AND a clip, you should choose both answers. |
| 01.02.2021 | Please describe the meaning of “intraoperative localization”. | “Intraoperative localization“ = specific search for the marker, for example using intraoperative ultrasound or magnetic or |

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| | | radar probe during the operation (but not during preparing for surgery).<br>In contrast, wire-guided localization is a preoperative localization technique and usually does not involve an additional intraoperative localization step. |
| 01.02.2021 | Can I change the “Form Status” after reply to a query? (yellow to green) | No. Please leave the status of the eCRF form as “Unverified” (yellow). The Monitor will change the status after evaluating your answer to the query. |
| 16.02.2021 | We use Magseed for marking the target lymph node; this is inserted prior to chemotherapy and is detected with a magnetic tracer. How should we answer the questions about preoperative and intraoperative localization? | Properative localization – not performed<br>Why not? Unnecessary due to planed intraoperative localization<br>Intraoperative localization attempted: yes, using a magnetic probe |
| 03.03.2021 | Is it possible to enroll patients participating in another trial in AXSANA? | In most cases, yes. However, it depends on the design of the other study, so please contact the Organizing Committee of AXSANA to discuss it. |
| 05.03.2021 | Is there grade 4 breast cancer? Possible answers for grading are: 1, 2, 3, 4. | The study sites should use the grading classification they use in the clinical routine. Most countries use Nottingham scoring system (1 to 3) but in some study sites other scores are used, and in case of completely dedifferentiated tumors grade 4 might be reported by the pathology.<br>Please choose the grading reported by your pathology - if you are using the Nottingham score it will be 1, 2 or 3. |
| 01.04.2021 | Is there a possibility to inform the study site, if there’s a new query? | Unfortunately no.<br>Please check the Redcap platform more often to see new queries. |
| | Should we mark **all** suspect lymphnodes? | There’s no standard. Please act like you do in normal clinical practice. |

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| | Is there's a maximum of pretherapeutic suspect lymph nodes for enroll the patient? | No.<br><br>But please see the exclusion criteria:<br>Confirmed or suspected supraclavicular or parasternal lymph node metastasis. |
| | Who is able to educate and enroll the patients? | The physician must be listed at the Signature & Delegation-Log. |
| | Do we need for each lymph node one pathological report? | No. One report is enough. |
| | intraoperative differentiation between SLN and TLN:<br><br>Do we have to differentiate in one resectate the TLN and the SLN? | Yes, if it's possible with small effort.<br>Otherwise send the hole resectate to the pathologist. |
| | Do we have to send the TLN for radiography? | No, you mustn't. Please act like you do in normal clinical practice. |
| 20.05.2021 | How should the radiation therapy be documented in case "high tangent" has been recommended by the radiation oncologist? | In this case, please ask your radiation oncologist which fields exactly are going to be irradiated as part of planning target volume (e.g., axilla level I, II etc.). |
| 21.06.2021 | In case of „ycN+" – do the patients have to complete the follow-up LQ-questionnaires? | No.<br><br>Only the ycN0-patients stay in the follow-up, no matter if they are ypN0 or ypN+. |
| | The patient gets 12x taxan and 4x anthracycline. How should we document this in the eCRF?<br><br>Should the Her2-therapy also be added? | Please add this together in the eCRF as 16x chemotherapy cycles.<br><br>No, please don't add the Her-2-therapy-cycles. |
| | Can we include a patient, who has already get the tumor extirpation, but no lymphonodectomy? | No, that's not possible. |

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| | How should we document a „drop off“? | Therefore please see CRF 8 – there you can document the drop off.<br><br>You don’t have to complete the other CRF’s. |

**In case of further questions, you can contact:**

Prof. Dr. T. Kühn: t.kuehn@klinikum-esslingen.de

PD Dr. M. Banys-Paluchowski: m.banys@outlook.com

Dr. S. Hartmann: steffi.hartmann@kliniksued-rostock.de

Dr. B. Aktas Sezen: aktas@eubreast.com

Ms. J. Shabbir: shabbir@eubreast.com