



## **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
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”	<p>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.</p> <p>Keep in mind that patients need to complete baseline QoL questionnaires within 4 weeks <u>before</u> the surgery (i.e. between 4 weeks before surgery and the day of surgery).</p>
18.02.2021	Is it really necessary to confirm lymph node metastasis by FNA/core biopsy?	<p>No.</p> <p>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.</p>
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”?	<p>No. You should choose “Clip” only if you used a non-magnetic not-radioactive clip. In case of MagSeed please chose “magnetic seed”.</p> <p>Of course, if you inserted both MagSeed <u>AND</u> a clip, you should choose both answers.</p>
01.02.2021	Please describe the meaning of “intraoperative localization”.	<p>“Intraoperative localization“ = specific search for the marker, for example using intraoperative ultrasound or magnetic or radar probe during the operation (but not during preparing for surgery).</p> <p>In contrast, wire-guided localization is a</p>

		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?	Preoperative localization – not performed Why not? Unnecessary due to planned intraoperative localization 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.

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

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