

**Nodal recurrence following axillary downstaging with neoadjuvant chemotherapy and omission of axillary lymph node dissection (OPBC-04/EUBREAST-06)**

**Study design:** Multicenter retrospective cohort study

**Population:** Biopsy proven N+ breast cancer who achieved nodal pCR after neoadjuvant chemotherapy and did not undergo axillary lymph node dissection

**Eligibility:**

- At least 1-year follow-up (inclusion period until end of 2020)
- Use of sentinel lymph node (SLN) procedure with dual mapping or targeted axillary dissection (TAD: imaging-guided localization of sampled node in combination with SLN procedure with or without dual mapping)
- Site must include a minimum of 10 cases

**Primary outcome:** Rate of nodal recurrence

**Secondary outcomes:** Rate of local and distant recurrence and overall survival

**List of variables to be collected:**

- Center
- Technique used to stage the axilla after NAC:
  - SLNB y/n
    - dual mapping (mandatory in case of SLN only without TAD)
    - single mapping (only allowed in case of TAD)
  - Imaging-guided localization of sampled node y/n
    - Type of imaging:
      - US only y/n
    - Type of localization:
      - wire/seed/tattoo/others
  - TAD y/n
- Sampled node clipped y/n
  - If yes: Clipped node removed y/n/unknown (documented by specimen radiography or operative/pathology reports)
- Number of negative SLNs
- Number of negative non-SLNs
- Date of surgery
- Age (at surgery)
- Ethnicity
- cT

- cN
- Histology (NST/lobular/other)
- Tumor grade
- Receptor status
  - ER pos and/or PR pos HER2neg;
  - ERneg/PRneg/HER2neg;
  - ERpos and/or PR pos/Her2pos;
  - ERneg/ PRneg Her2pos)
- Type of NAC regimen (Taxan/Anthracyclin/Platin containing)
- Type of anti-HER2 therapy (Trastuzumab alone/Trastuzumab+Pertuzumab/other)
- Type of breast surgery: BCT/mastectomy
- Date of surgery
- Breast pCR: yes/no
- Nodal pCR: yes/no (should be excluded if no)
- Adjuvant capecitabine: yes/no
- If HER2+: type of post-surgical anti-HER2 treatment (H/HP/TDM-1)
- If HR+: received adjuvant endocrine therapy: yes/no, if yes: type of endocrine therapy

Radiotherapy: yes/no

- Target Volume:
  - Whole breast irradiation: y/n
  - Thoracic wall irradiation: y/no
  - Regional nodal irradiation y/no
- Date of last follow up
- Recurrence: yes/no
- Type of recurrence: local/regional/locoregional/distant
- Type of regional recurrence: axillary only, axillary and supraclavicular or internal mammary, supraclavicular or internal mammary without axillary
- Date of recurrence
- Deceased: yes/no
- Date of death
- Cause of death

Local PI	City, Country	Estimated accrual	Ethical approval	Data generation finished by	Data transferred	Supp Mat transferred
Montagna	MSKCC, NY, USA	250	yes	end of Feb 2022		
Mrdutt Mary	Mayo Clinic, Rochester, USA	160	pending	end of March 22		
Jens-Uwe Blohmer	Berlin, Germany		yes			
Jörg Heil	Heidelberg, Germany	40	yes		to Walter	
Florian Fitzal	Vienna, Austria	10	yes	end of Feb	to Walter	
Christoph Tausch	Zürich, Switzerland	45	pending	end of Feb 22		
Francesco Meani	Ticino, Switzerland		pending	end of Feb		
Laszlo Romics	Glasgow, United Kingdom	17	yes	end of Feb 22	to Walter	
Dedes	USZ, Switzerland	18	pending	end of Jan 22	to Walter	
Paulinelli	Goiania, Brazil	20	yes	end of Feb 22	to Walter to Giacomo	to Walter to Giacomo
Ovalle	IRAM, Chile	30	pending	end of Mar 22		
Rocco	Naples, Italy	10	yes	end of Feb 22	to Walter to Giacomo	to Walter to Giacomo
Atte Marcelo Chávez Díaz	Lima, Perú	29	pending	ethics end of Mar 22	to Walter	to Walter
Thorsten Kühn	Esslingen, Germany		pending			
Mathias Fehr	Frauenfeld, Switzerland	13	yes	end of Feb 22	to Walter to Giacomo	to Walter to Giacomo



Maggie Banys-Paluchowski	Lübeck, Germany	20	yes	Mar 22		
Ditsch	Augsburg, Germany	10	pending	Mar 22		
Astrid Botty van den bruele	Duke, NC, USA	23	pending	end of Dec 21	to Giacomo	to Giacomo
Weber	Basel, Switzerland	34	yes	end of Feb 2022	to Giacomo	to Giacomo
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