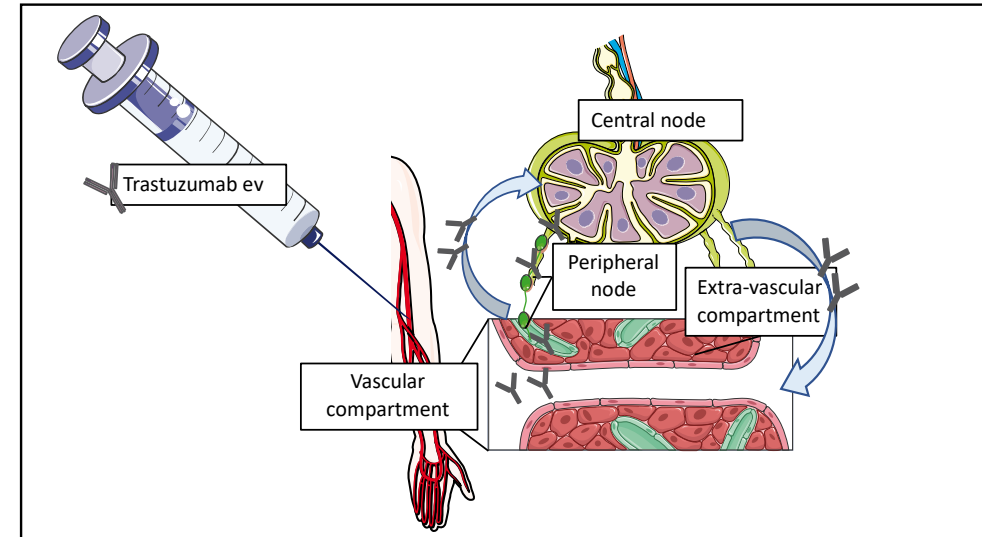
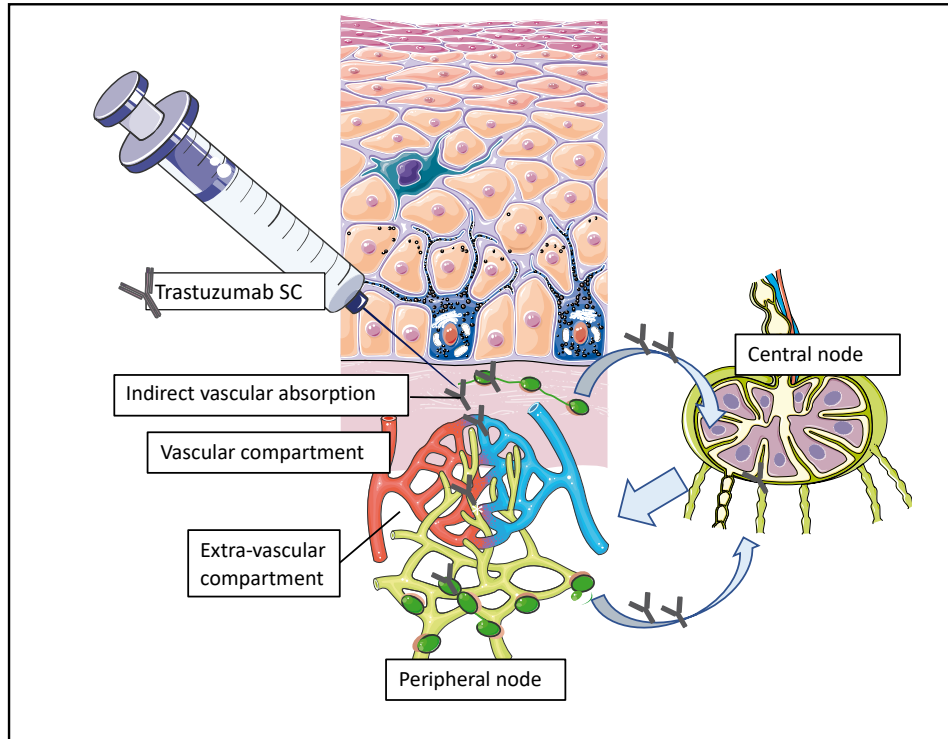


## Randomized, Open Label, Phase II, Biomarker Study of Immune-mediated Mechanism of Action of Neoadjuvant Subcutaneous Trastuzumab in Patients with Locally Advanced, Inflammatory, or Early HER2-positive Breast Cancer- Immun-HER trial (GOIRC-01-2016)



### Authors

B Pellegrino & C Tommasi, O Serra, S Gori, E Cretella, M Ambroggi, A Frassoldati, G Bisagni, C Casarini, E Bria, L Carbognin, E Fiorio, A Mura, C Zamagni, L Gianni, A Zambelli, F Montemurro, M Tognetto, R Todeschini, G Missale, N Campanini, EM Silini, G Maglietta & A Musolino.

### Correspondence

antonino.musolino@unipr.it

### In brief

- **Study population:** 63 patients with locally advanced, inflammatory or early stage, unilateral and histologically confirmed invasive HER2+ BC.
- **Statistical design:** In this multicenter randomized phase II trial, the primary endpoint was the proportion of patients with high stromal tumor-infiltrating lymphocytes (sTILs) after neoadjuvant chemo-immunotherapy (NAT) containing pertuzumab plus IV trastuzumab (arm A) or pertuzumab plus SC trastuzumab (arm B).
- **Results:** SC trastuzumab exerted the most relevant enrichment of sTILs, with favorable variations of immune parameters in HER2-positive residual disease after NAT. Novel immunotherapy strategies should be tested to achieve SC-specific, antitumor immune response.