PS5-09-08: DespaTIL Study: A Phase II Trial of De-escalated Neoadjuvant Chemotherapy for Early-Stage Triple-Negative Breast Cancer Guided by Tumor-Infiltrating Lymphocytes (TILs) and Radiologic Response

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BACKGROUND

Currently, a four-chemotherapy drug regimen (plus pembrolizumab if stage II-III), is frequently used as neoadjuvant treatment for triple-negative breast cancer (TNBC) (1). These regimens are associated with high toxicity rates, and, given the heterogeneity of the disease, some patients may achieve favorable outcomes with less intensive treatment strategies (2). In this context, high levels of tumor-infiltrating lymphocytes (TILs) have been identified as a marker of excellent prognosis (3). Additionally, radiologic response can assist in treatment decision-making, allowing escalation only for patients whose tumors do not respond well, thereby optimizing therapy (4). The DespaTIL study investigates a biomarker-driven de-escalation approach to neoadjuvant chemotherapy (NAC) in early-stage TNBC.

OBJECTIVE

TTo evaluate the short-term efficacy of a de-escalated neoadjuvant treatment regimen guided by disease stage, tumor-infiltrating lymphocytes (TILs), and radiological response.

METHODS

DespaTIL is a multicenter, single-arm, investigator-initiated phase II trial evaluating a de-escalated NAC strategy in patients with stage I TNBC with any level of TILs, or stage II TNBC with ≥50% stromal TILs. All patients receive four cycles of carboplatin and a taxane. Radiologic response is assessed via breast magnetic resonance imaging after cycle 4. Patients whose tumors achieve a radiologic complete response proceed to surgery. Those whose tumors do not achieve a radiologic complete response receive four additional cycles of anthracycline and cyclophosphamide (AC), with or without pembrolizumab. A total of 40 patients will be enrolled.

MAIN ELIGIBILITY CRITERIA

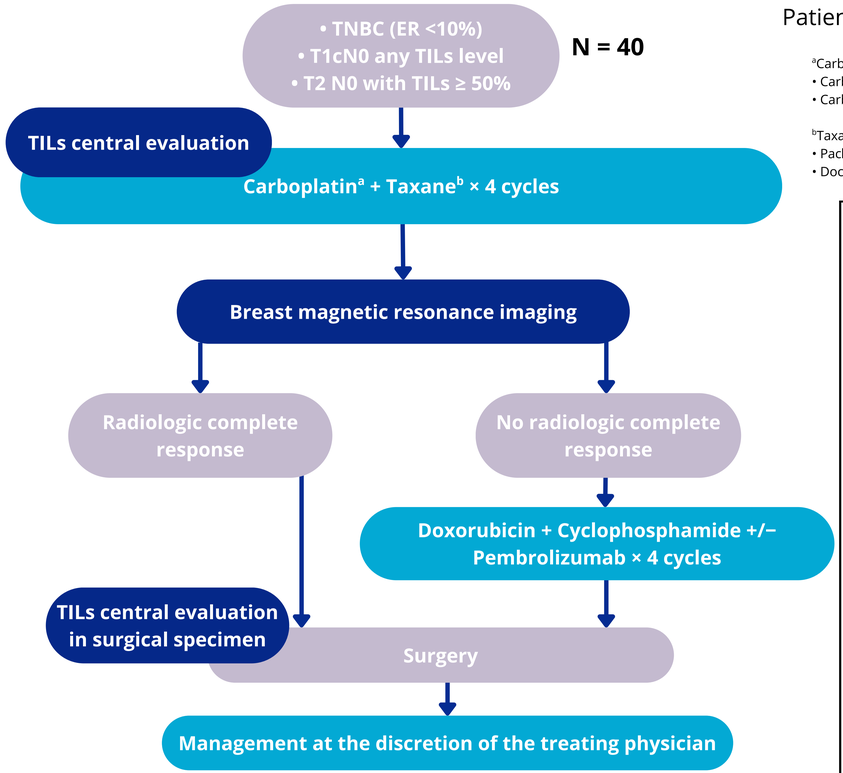
- Patients with HER2-negative hormone receptor-negative or low (estrogen receptor and progesterone receptor expression <10%) invasive breast carcinoma, and one of the following:

(1) **clinical stage T1c N0 M0 with any TIL level;** or

(2) **clinical stage T2 N0 M0 with TILs ≥50%**.

- Age ≥ 18 years.
- ECOG performance status 0 to 2.

STUDY GRAPHICAL ABSTRACT



CURRENT STATUS

NCT07074106

Patient enrollment is now open.

[a]Carboplatin may be performed with one of the options:
- Carboplatin AUC 1.5 D1, D8, D15, intravenous, every 21 days, or;
- Carboplatin AUC 5 D1, intravenous, every 21 days,

[b]Taxane may be performed with one of the options:
- Paclitaxel 80 mg/m 2 D1, D8, D15, intravenously, every 21 days, or;
- Docetaxel 75 mg/m 2 D1, intravenous, every 21 days.

Primary endpoint

Pathologic complete response (pCR), defined as ypT0-ypTis ypN0, following four cycles of carboplatin and taxane

Secondary endpoints

- Accuracy of magnetic resonance imaging as a predictor of pathological response;
- pCR in the overall study population;
- Residual cancer burden burden (RCB): 1) surgery after 4 cycles of carboplatin and paclitaxel; 2) overall study population;
- Event-free survival (EFS) in the cohorts: 1) surgery after 4 cycles of carboplatin and paclitaxel, 2) overall study population;
- Overall survival (OS) in the cohorts: 1) surgery after 4 cycles of carboplatin and paclitaxel , 2) overall study population.

References:
1. Schmid P, et al. N Engl J Med. 2020;382(9):810-821.
2. Andrade MO, et al. The Breast. 2025 Oct;83:104473.
3. de Jong VM, et al. Journal of Clinical Oncology 2022;40:2361-2374.
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