Figure 1. Study design.

RESULTS

Patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>FAC (n=744)</th>
<th>TAC (n=746)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>57.9 (10.1)</td>
<td>58.2 (10.0)</td>
</tr>
<tr>
<td>Menopausal status</td>
<td>Premenopausal: 61.7% vs 52.4%</td>
<td>Premenopausal: 61.7% vs 52.4%</td>
</tr>
<tr>
<td>Primary prophylaxis</td>
<td>57% vs 47%</td>
<td>57% vs 47%</td>
</tr>
<tr>
<td>Neutropenic events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutropenic infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Febrile neutropenia</td>
<td></td>
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</tbody>
</table>

Figure 2. Kaplan-Meier curves for cumulative probability of neutropenic infection by treatment assignment (log rank).

CONCLUSIONS

- Neutropenic events were more frequent on TAC than FAC but no acute deaths were observed.

- Secondary prophylaxis with G-CSF resulted in reduction of febrile neutropenia.

- Primary prophylaxis with G-CSF might also be effective in reducing rates of fever neutropenia. Data from trials with TAC as adjuvant treatment — both already completed (GEICAM 9805, BCIRG 005) and ongoing (NSABP B30) — are needed to confirm these results.

ABSTRACT

Background: This trial was designed to assess efficacy and overall survival in patients with hormone receptor-positive node-negative breast cancer treated with FAC (5-fluorouracil–doxorubicin–cyclophosphamide) or TAC (docetaxel–doxorubicin–cyclophosphamide) in the adjuvant setting as compared with FAC in the neoadjuvant setting. FAC and TAC are both recognized as active regimens for early stage breast cancer. The endpoints of this trial were overall survival and disease-free survival.

Methods: A total of 1491 patients were randomized to FAC or TAC in a 2:1 ratio. All patients had hormone receptor-positive node-negative breast cancer. FAC was administered at a dose of 500 mg/m² for 5-fluorouracil, 50 mg/m² for cyclophosphamide, and 60 mg/m² for doxorubicin every 3 weeks. TAC was administered at a dose of 75 mg/m² for docetaxel, 50 mg/m² for cyclophosphamide, and 50 mg/m² for doxorubicin every 3 weeks. Neutropenic events were more frequent on TAC than FAC, but no acute deaths were observed. Secondary prophylaxis with G-CSF resulted in reduction of febrile neutropenia.

RESULTS: A total of 1491 patients were randomized to FAC or TAC in a 2:1 ratio. All patients had hormone receptor-positive node-negative breast cancer. FAC was administered at a dose of 500 mg/m² for 5-fluorouracil, 50 mg/m² for cyclophosphamide, and 60 mg/m² for doxorubicin every 3 weeks. TAC was administered at a dose of 75 mg/m² for docetaxel, 50 mg/m² for cyclophosphamide, and 50 mg/m² for doxorubicin every 3 weeks. Neutropenic events were more frequent on TAC than FAC, but no acute deaths were observed. Secondary prophylaxis with G-CSF resulted in reduction of febrile neutropenia.

CONCLUSIONS: Neutropenic events were more frequent on TAC than FAC but no acute deaths were observed. Secondary prophylaxis with G-CSF resulted in reduction of febrile neutropenia. Primary prophylaxis with G-CSF might also be effective in reducing rates of febrile neutropenia. Data from trials with TAC as adjuvant treatment — both already completed (GEICAM 9805, BCIRG 005) and ongoing (NSABP B30) — are needed to confirm these results.

METHODS

- The study design is summarized in Figure 1.

- Primary prophylaxis with granulocyte colony-stimulating factor (G-CSF) (ie from the first cycle) was not permitted.

- The use of G-CSF was permitted.

- Primary prophylaxis treatment in patients of delayed neutropenia or infection.

- Prophylactic treatment in patients with a previous episode of grade neutropenia in a similar cycle.

- Treatment for delayed recovery of neutrophils at Day 21.

Figure 3. Kaplan-Meier curves for cumulative probability of neutropenic infection by treatment assignment (log rank).