Di Leo 2008

NCT00075270

1 Treatments

Studied treatment  first-line therapy with paclitaxel 175 mg/m(2) every 3 weeks plus lapatinib 1,500 mg/d

Control treatment  paclitaxel

Concomittant treatments  -

2 Patients

Patients  first-line treatment for metastatic breast cancer

Inclusion criteria  -

Exclusion criteria  -

HER2-positive  15%

3 Methods

Blinding  double-blind

Design  Parallel groups

Centers  -

Geographical area  -

Sizes  579/0

4 Results

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
<th>d</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>clinical benefit</td>
<td>-/579</td>
<td>-/0</td>
<td>NA</td>
<td>-</td>
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<td>progression (time to progression, TTP)</td>
<td>-/579</td>
<td>-/0</td>
<td>NA</td>
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<td>PFS</td>
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<td>-/0</td>
<td>0,90</td>
<td>[0,75; 1,08]</td>
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<td>OS</td>
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<td>0,86</td>
<td>[0,69; 1,08]</td>
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<td>ORR</td>
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<td>NA</td>
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<td>SAE</td>
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<td>-/0</td>
<td>1,65</td>
<td>[1,16; 2,35]</td>
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5 References


Finn RS, Press MF, Dering J, Arbushites M, Koehler M, Oliva C, Williams LS, Di Leo A. Estrogen receptor, progesterone receptor, human epidermal growth factor receptor 2 (HER2), and epidermal growth factor receptor expression and benefit from lapatinib in a randomized trial of paclitaxel with lapatinib or placebo as first-line treatment in HER2-negative or unknown metastatic breast cancer. J Clin Oncol 2009;27:3908-15 [19620495]