BOLERO-2 2011

NCT00863655

1 Treatments

Studied treatment everolimus and exemestane

Control treatment exemestane and placebo

Concomittant treatments exemestane

2 Patients

Patients patients with hormone-receptor-positive advanced breast cancer who had recurrence or progression while receiving previous therapy with a nonsteroidal aromatase inhibitor in the adjuvant setting or to treat advanced disease (or both).

Inclusion criteria -

Exclusion criteria -

3 Methods

Blinding double-blind

Design Parallel groups

Centers -

Geographical area -

Sizes 485/239

stage -

4 Results

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
<th>d</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFS</td>
<td>-485</td>
<td>-239</td>
<td>0,43</td>
<td>[0,35; 0,53]</td>
</tr>
<tr>
<td>OS</td>
<td>-485</td>
<td>-239</td>
<td>0,89</td>
<td>[0,73; 1,09]</td>
</tr>
<tr>
<td>Time to progression (TTP)</td>
<td>-485</td>
<td>-239</td>
<td>NA</td>
<td>-</td>
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</tbody>
</table>
5 References

