OVER 2009

NCT00094575

1 Treatments

**Studied treatment**  endovascular repair
devascular systems approved by the FDA (Cook Zenith 39%, Gore Excluder 37%)

**Control treatment**  open repair

**Concomittant treatments**  Aspirin 59%, beta-blockers 64%, anticoagulants 9%, ACEI 42%

2 Patients

Patients  men (aged >=49 years) with abdominal aortic aneurysms candidate for both both elective endovascular repair and open repair

**Inclusion criteria**  maximum external diameter >5 cm; associated iliac aneurysm with a maximum diameter of at least 3.0 cm; maximum diameter of at least 4.5 cm plus either rapid enlargement (at least 0.7 cm in 6 months or 1.0 cm in 12 months) or saccular morphology; manufacturer’s indications for the endovascular system that would be used if so assigned

**Exclusion criteria**  previous AAA repair; need for urgent repair

**concomitant coronary artery disease**  41%

**history of cerebrovascular accident**  16%

**low surgical risk score**  53%

3 Methods

**Blinding**  open

**Design**  Parallel groups

**Centers**  42

**Geographical area**  USA

**Sizes**  444/437

**aneurysm diameter**  5.7 cm mean
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>death from any cause and reintervention</td>
<td>-/444</td>
<td>-/437</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>In hospital aneurysm-related death</td>
<td>-/444</td>
<td>-/437</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>30-day death</td>
<td>1/444</td>
<td>10/437</td>
<td>0,10</td>
<td>[0,01; 0,77]</td>
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<td>Long term mortality</td>
<td>31/444</td>
<td>43/437</td>
<td>0,71</td>
<td>[0,44; 1,15]</td>
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<td>long term aneurysm-related death</td>
<td>-/444</td>
<td>-/437</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>In hospital death</td>
<td>2/444</td>
<td>13/437</td>
<td>0,15</td>
<td>[0,03; 0,68]</td>
</tr>
</tbody>
</table>

5 References

Lederle FA, Freischlag JA, Kyriakides TC, Padberg FT Jr, Matsumura JS, Kohler TR, Lin PH, Jean-Claude JM, Cikrit DF, Swanson KM, Peduzzi PN Outcomes Following Endovascular vs Open Repair of Abdominal Aortic Aneurysm: A Randomized Trial. JAMA 2009;302:1535-1542 [19826022]