CLOSURE I 2010

NCT00201461

1 Treatments

Studied treatment  patent foramen ovale closure using the Starflex device

Control treatment  best medical therapy: aspirin (325 mg daily) and/or warfarin (target INR = 2.5)

Concomittant treatments  -

2 Patients

Patients  patients with a stroke and/or transient ischemic attack due to presumed paradoxical embolism through a patent foramen ovale

Inclusion criteria  age 18-60 years inclusive; positive contrast valsalva bubble study by trans-esophageal echocardiogram (TEE) for patent foramen ovale (PFO), with or without atrial septal aneurysm; stroke or clinically definite TIA (contact study coordinator); be able to comply with follow up over two years; be competent to, or have a legal guardian competent to, provide informed consent following full disclosure of risks and benefits of both treatment arms by a study investigator; venous access capable of accepting a 10F minimum vascular sheath; have, or be willing to, discontinue hormonal based contraceptive use prior to enrollment and for the term of the study; has cardiac anatomy based on enrollment echocardiogram that will allow for placement of the implant if randomized to the implant arm;

Exclusion criteria  see protocol

3 Methods

Blinding  open

Design  Parallel groups

Centers  87

Geographical area  US, Canada

Sizes  447/462
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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</thead>
<tbody>
<tr>
<td>major vascular complication</td>
<td>13/447</td>
<td>0/462</td>
<td>27.91</td>
<td>[1.65; 470.88]</td>
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<td>Afib</td>
<td>23/447</td>
<td>3/462</td>
<td>6.94</td>
<td>[2.24; 21.50]</td>
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<td>stroke or TIA, all death at 30d, neurological death</td>
<td>23/447</td>
<td>29/462</td>
<td>0.82</td>
<td>[0.47; 1.44]</td>
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<td>stroke</td>
<td>12/447</td>
<td>13/462</td>
<td>0.96</td>
<td>[0.44; 2.09]</td>
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<td>TIA</td>
<td>13/447</td>
<td>17/462</td>
<td>0.80</td>
<td>[0.39; 1.64]</td>
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5 References
