meriT-V Study

Study Highlights

- Principal Investigator: Dr. Alexandre Abizaid
- The meriT-V is a prospective, multicentre, randomized, open-label, active-controlled, non-inferiority trial of the BioMime sirolimus-eluting coronary stent system (SES) as compared to the XIENCE family of everolimus-eluting coronary stents in the treatment of patients with de novo native coronary artery lesions
- Two years clinical follow-up including angiographic analysis at 9 months.
- BioMime SES was non-inferior to XIENCE EES for the primary endpoint of in-stent late lumen loss
Study Design
- A prospective, multicentre, randomized, open-label, active-controlled, non-inferiority trial

256 patients were enrolled and randomly assigned (2:1) to BioMime SES or XIENCE EES between November 2014 and December 2016

15 investigational sites in Europe (12 sites, including the Netherlands, Belgium, UK, Spain, Latvia, Macedonia, Czech Republic, and Poland) and Brazil (3 sites)

Clinical follow-up at 30 days, 5 months, 9 months, 12 months and 24 months post-procedure

Angiographic follow-up at 9-month
Analysed by Cardiovascular Research Centre, Sao Paulo, Brazil

Study Results

Late Lumen Loss at 9 Months Follow-up

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<thead>
<tr>
<th>IN-STENT</th>
<th>IN-SEGMENT</th>
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<tr>
<td>BioMime</td>
<td>0.15</td>
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<td>Xience</td>
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Late Lumen Loss (mm)
Cumulative event curve of MACE

Cumulative event curve of MI
References

in Patients With De Novo Native Coronary Artery Lesions: The meriT-V Randomized Trial, At TCT-2018.