FOREST trial

a randomized controlled trial comparing drug-eluting balloons and drug-eluting stents in femoropopliteal arterial occlusive disease

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Disclosure

I have the following potential conflicts of interest to report:

- I do not have any potential conflict of interest
Rationale

Femoropopliteal angioplasty

Uncoated balloon angioplasty disappointing (UCB)

Improvement in outcomes:
- Stents (bare-metal, covered, drug-eluting stent)
- Drug-eluting balloon
Rationale

If DEB $\approx$ DES

$\rightarrow$ Choose DEB while..,

- DEB: nothing is left behind
- DES: Stent fracture, Stent thrombosis, Reintervention?

To date *no RCT* comparing DEB vs DES in the femoropopliteal arteries available
FOREST trial

Randomized comparison of FemORopopliteal artery drug-Eluting balloons and drug-eluting STents (FOREST)

Prospective
Randomized controlled trial
Multicenter
DEB vs DES
Non-inferiority
Femoropopliteal arteries
Devices

DEB group:
In.Pact admiral DEB
Medtronic, Minneapolis, Minnesota

DES group
Zilver PTX DES
Cook Medical, Bloomington, Indiana
Sample size calculation

Freedom from binary restenosis rate (2 years):
80.2% (In.Pact Admiral) vs 74.8% (Zilver PTX)

Non-inferiority trial
Power of 80% = 115 patient per arm
10% loss to follow up → 127 patients per arm

Inclusion = 254 patients (1:1)
## Patients

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Rutherford-Baker 2-5</td>
<td>Life expectancy &lt;2 year</td>
</tr>
<tr>
<td>De novo stenotic or occlusive lesion</td>
<td>Recurrent stenosis or occlusion</td>
</tr>
<tr>
<td>SFA or popliteal artery (only p1)</td>
<td>Acute femoropopliteal occlusion</td>
</tr>
<tr>
<td>1 patent tibial runoff vessel</td>
<td>Aspirin, clopidogrel, heparin or paclitaxel allergy</td>
</tr>
<tr>
<td>Reference diameter of 4-7 mm</td>
<td></td>
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<tr>
<td>Successful passage with guidewire</td>
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Endpoints

Primary:
• Freedom from binary restenosis after 2 year (<50% lumen reduction assessed by duplex ultrasound, PVR<2.5)

Secondary:
• Technical success
• TLR
• TVR
• ABI improvement
• Improvement in Rutherford classification
• Amputation rate
• Mortality rate
Procedure

Patients with potential AFS or P1 lesion

Digital subtraction angiography

Randomization

DEB-group
DEB + bail-out spot-stenting (persisting residual stenosis >30% or flow limiting dissection (5 min.))

DES-group
Primary stenting with DES

Medical therapy:
Clopidogrel (lifelong)
Aspirin (3 months)
Statine (lifelong)
## Follow up

<table>
<thead>
<tr>
<th></th>
<th>1 month</th>
<th>6 months</th>
<th>12 months</th>
<th>24 months</th>
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<tbody>
<tr>
<td>Outpatient clinic visit</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Questionnaire</td>
<td>X</td>
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<td>Treadmill test</td>
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<tr>
<td>Duplex ultrasound</td>
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Questionnaire: Peripheral Artery Questionnaire (PAQ)
Current status

17/254 patients enrolled since 15-09-2016 in 1 centre

Per 01-02-2017 approval in 3 centres.

More to come..!

Maasstad Hospital, Rotterdam, NL
St. Antonius Hospital, Nieuwegein, NL
Noordwest ziekenhuisgroep, Alkmaar, NL

Aim: Enrollment complete september 2018
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