CONSEQUENT All Comers Registry

DCB performance under real world conditions

ongoing recruitment

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

X  I do not have any potential conflict of interest
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Objective

To assess the safety and efficacy of the paclitaxel-releasing balloon catheter SeQuent® Please OTW to treat de novo and restenotic lesions (no ISR) in peripheral arteries (ATK, BTK) in an unselected patient population.
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Device: SeQuent® Please OTW

- Drug: Paclitaxel (3μg/mm²)
- Excipient: Resveratrol
  (naturally occurring, plant based substance, anti-inflammatory, antioxidant & anti-hypertensive characteristics¹,²)
- 014-Version: Ø 1.5 – 3.0 mm ; ↔ 40 – 150 mm
- 035-Version: Ø 4.0 – 8.0 mm ; ↔ 40 – 150 mm

¹ Ciccone G et al. Anti-Inflammatory and Antioxidant Effects of Resveratrol in Healthy Smokers A Randomized, Double-Blind, Placebo-Controlled, Cross-Over Trial. 2013
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Procedure

It is the intention of this trial to treat suitable target lesions with DCB only.

Predilatation at the discretion of the investigator, but mandatory only in total occlusions.
Patients and lesions

- Rutherford classes 2 through 5
- Peripheral lesions (≥1) in peripheral arteries above and below the knee
- Reference vessel diameters between 1.5 and 8.0 mm, lesion lengths ≥ 2 cm and ≤ 27 cm as angiographically documented
- Vessels must have adequate runoff with at least one vessel to the foot.
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**Primary Endpoint**
- TLR at 12 months

**Secondary Endpoints**
- TLR at 24 months
- ABI at 12 and 24 months
- Walking Distance at 12 and 24 months
- Patency (Duplex ultrasound at 12 and 24 months)
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A priori defined subgroups

- BTK and ATK
- DCB only
- DCB + Stent
- CLI patients
- diabetics
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Recruitment

302 patients as of January 18, 2017

- Germany (255 patients)
- Spain (38 patients)
- Malaysia (9 patients)

Estimated Enrollment: 500 patients
Combination therapy DCB + MSDS

Further investigation within the registry:

Treatment of DCB first, followed by Multiple Stent Delivery System

SeQuent® Please OTW + VascuFlex® Multi-LOC
Thank you for your attention
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