SirPAD
The largest randomised trial with a sirolimus-coated balloon for peripheral arterial disease

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Disclosure

Speaker’s name: Stefano Barco

I have the following potential conflicts of interest to report:

- [x] Consulting: Boston Scientific, Bayer Healthcare
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [x] Other(s): Daiichi Sankyo, Bayer (travel costs); Sanofi (institutional grant)
Rationale of the SirPAD RCT
Registration: NCT04238546

- Characteristics of product (sirolimus-coated)
- Trials with surrogate outcomes and many exclusion criteria
- Prior PCI experience
- Unclear impact of paclitaxel-balloons on long-term survival
Key eligibility criteria

➢ Endovascular angioplasty needed for infrainguinal PAD (all-comer study)
➢ No participation in other studies

**Target lesion:** the main lesion considered responsible for signs and symptoms; **angiographic criteria:**

- 1) stenosis (lumen compromise ≥50%) in at least a single plane of the femoro-popliteal arterial segment or a femoropopliteal bypass, or
- 2) stenosis (lumen compromise ≥50%) of the below-the-knee arterial segment or a below the knee bypass
Study groups

**INTERVENTION**
Magic Touch PTA sirolimus-coated balloon

**COMPARATOR**
Any available CE-certified uncoated balloon catheter approved for PAD

Randomization ratio 1:1
Primary efficacy outcome

A composite of two major adverse limb events (MALE)

(i) **unplanned major amputation** of the target limb
(ii) endovascular or surgical target lesion **revascularization for critical limb ischemia**

within one year of enrolment.
Key secondary and safety outcomes

- Unplanned minor amputation at target limb
- Unplanned major amputation at target limb
- Any target lesion re-vascularization
- Target lesion re-vascularization for critical limb
- Death from all causes
- Death and MALE
- SAEs
- SADEs
Study flow

**Informed consent and clinical screening**

**Angiographic screening**

- Sirolimus-coated endovascular treatment
- Non-coated endovascular treatment

**Primary efficacy outcome (major adverse limb events)**
- Major amputation (above the knee) not previously planned
- Target limb revascularization for critical limb ischemia (Fontaine ≥III)

Patients, relatives, and treating physicians will be instructed to refer to the hub hospital if signs or symptoms of critical limb ischemia.

**V1: Day -90 to Day 0**
- Outpatients
- Satellite hospitals
- Emergency room
- External vascular meds
- Inpatients

**V2: Day 1**
- Cath-lab

**V3: Discharge**
- In-hospital

**V4: Day 30-180**
- In-hospital office visit or telephone contact; (administrative data)

**V5: Day 365**
- In-hospital office visit or telephone contact; (administrative data)

**V6: Day 730**
- Administrative data; (telephone contact)

**Mortality**
Hierarchical analysis

Non-inferiority for the primary efficacy outcome within one year

if confirmed, pre-specified hierarchical analysis:

a) superiori\textit{"y for the composite of unplanned (major or minor) index-limb amputations and any target lesion re-vascularization} within one year (\(\alpha=2.5\%\) one-sided)

b) \textit{superiority for the primary efficacy outcome} within one year (\(\alpha=2.5\%\) one-sided)

\textbf{Populations}: intention-to-treat, as-treated, per-protocol.
Sample size and status

**Assumption**

10% event rate (MALE) within one year

**Non-inferiority margin**

5% (absolute risk difference)

**Sample size**

1200 patients
(566 patients per treatment group plus drop-outs)

**Status:** n=77 patients enrolled in 2.5 months (despite COVID-19).
Interim analysis after 600 patients.

*Publication of the study design paper pending.*
Many thanks for your attention

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First patient randomized in the SirPAD study on 03. Nov 2020