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:

☒ Consulting: Boston Scientific, Bayer Healthcare

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☒ 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

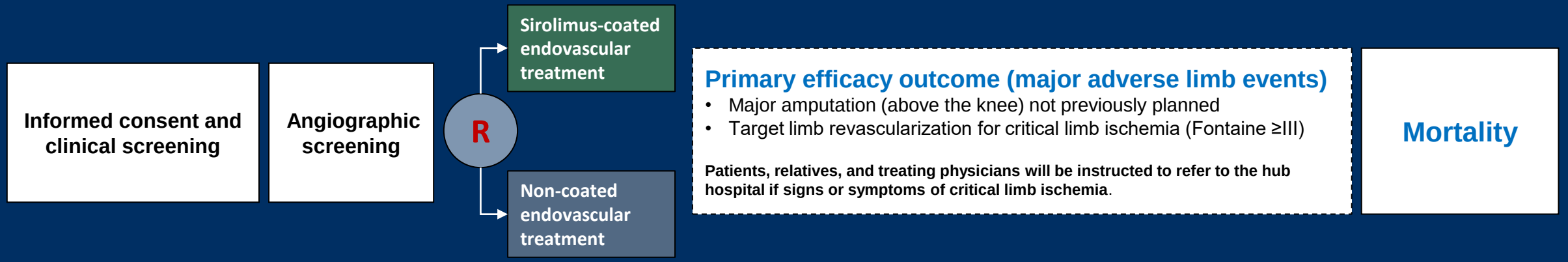
(ii) endovascular or surgical target lesion **revascularization for critical limb ischemia**

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



***V1**: Day -90 to Day 0*	***V2**: Day 1*	***V3**: Discharge*	***V4**: Day 30-180*	***V5**: Day 365*	***V6**: Day 730*
➢ Outpatients ➢ Satellite hospitals ➢ Emergency room ➢ External vascular meds ➢ Inpatients	Cath-lab	In-hospital	In-hospital office visit or telephone contact; (administrative data)	In-hospital office visit or telephone contact; (administrative data)	Administrative data; (telephonical contact)

Hierarchical analysis

Non-inferiority for the primary efficacy outcome within one year

if confirmed, pre-specified hierarchical analysis:

a) **superiority for the composite of unplanned (major or minor) index-limb amputations and any target lesion re-vascularization** within one year (α=2.5% one-sided)

b) **superiority for the primary efficacy outcome** within one year (α=2.5% one-sided)

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

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

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