

Safety and Effectiveness of the Crystalline Sirolimus-Eluting Device in Patients With Coronary Artery Disease

NCT07444957

Status	RECRUITING
Sponsor	Fundación Interhospitalaria para la Investigación Cardiovascular FIC
Enrollment	1,118 participants

Key Eligibility Criteria

Inclusion (4)

- All patients must provide written informed consent.
- Patients aged e18 years with coronary artery disease in whom, at the operator's discretion, treatment of a coronary stenosis in a native vessel (either de novo lesion or in-stent restenosis) or in a coronary bypass graft using the cSCB is indicated, in accordance with routine clinical practice.
- All treated lesions/segments (single or tandem) must receive cSCB therapy covering at least 3 mm beyond both edges of the lesion or pre-dilated segment to avoid geographic miss.
- In patients with multivessel coronary artery disease, all non-target vessels will be treated according to operator discretion: a) If more than one vessel is treated with the investigational device (SeQuent® SCB), all vessels will be documented and analyzed separately. b) Only one lesion per vessel will be included unless lesions are separated by e20 mm. c) Only one lesion per vessel will be included. d) If more than one lesion in the target vessel requires treatment, all lesions treated with a device different from the investigational procedure or with a device other than the investigational device (SeQuent® SCB) must be separated from the target lesion by e20 mm or considered as a single treated lesion according to this study protocol.

Exclusion (12)

- Explicit refusal by the patient to participate in the study.
- Known intolerance to sirolimus or to any component of the investigational device.
- Contraindication to any antiplatelet therapy.
- Life expectancy less than 12 months.
- Indication for surgical coronary revascularization.
- ... and 7 more (see full listing online)

Locations (1 total)

Hospital Álvaro Cunqueiro, Vigo, Pontevedra, Spain