

Treatment of Functionally Non-significant Vulnerable Plaques in Patients With Multivessel ST-elevation Myocardial Infarction The VULNERABLE Trial

NCT05599061

Status	RECRUITING
Phase	Not Applicable
Sponsor	Fundación EPIC
Enrollment	600 participants

Key Eligibility Criteria

Inclusion (6)

- Patients \geq 18 years.
- Successful revascularization of the culprit lesion in patients undergoing coronary angiography due to ST-segment elevation (\geq 1mm in \geq 2 contiguous leads, new left bundle branch block, or true posterior MI with ST depression of \geq 1mm in \geq 2 contiguous anterior leads) in the first 72 hours of the symptom's onset.
- Multivessel coronary disease with non-culprit lesions located in different vessels than the culprit lesion and ranging from 40 to 69% of DS (visual estimated diameter stenosis) by visual estimate planned for FFR-guided revascularization in staged procedure (\geq 24 hours and \leq 60 days after PCI of the culprit lesion).
- Non-culprit lesions should be suitable for functional assessment with pressure wire and OCT catheter and should be suitable to be treated with a single 2.0 to 4.5 mm EES (everolimus-eluting stent).
- Subject agrees to not participate in any other clinical trial study for a period of 4 years following the inclusion in the study.

... and 1 more (see full listing online)

Exclusion (10)

- Inability to provide informed consent.
- Female of childbearing potential (age \leq 50 years and last menstruation within the last 12 months), who did not undergo tubal ligation, ovariectomy or hysterectomy.
- Known intolerance to aspirin, heparin, everolimus, contrast material.
- Unresolved mechanical complication or cardiogenic shock at the staged procedure.
- Non-culprit study lesions located in the left main coronary artery or in coronary vessels with prior coronary revascularization (PCI or by-pass) or with distal vessel occlusion.

... and 5 more (see full listing online)

Locations (49 total)

Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Barcelona, Spain

Hospital Universitario A Coruña, A Coruña, Spain

Hospital General Universitario de Albacete, Albacete, Spain

... and 46 more locations