Study Protocol

REVASCULARIZATION AFTER IMPLANTATION OF TRANSCATHETER AORTIC VALVE BIOPROSTHESIS

THE REVIVAL MULTICENTER REGISTRY

ClinicalTrials.gov Identifier:

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Coordinating centers:

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Clinical Study Proposal

Title	Revascularization after implantation of transcatheter aortic valve bioprosthesis
Acronym	REVIVAL
Background	The increasing operator experience combined with an improved performance of devices have led to extend current transcatheter aortic valve implantation (TAVI) indications to patients at low or intermediate risk (1-3). The safety of TAVI in this population was initially tested in small observational studies (4-7) and recently reported in the randomized PARTNER 2 and SURTAVI trials (8), which demonstrated non-inferiority of TAVI in low or intermediate risk patients as compared to surgery with respect to the primary endpoint of death or disabling stroke. In view of the changes in the TAVI population, including younger patients with longer survival, the number of patients that may require coronary revascularization after TAVI is expected to increase over the time. Of note, challenges in performing percutaneous coronary interventions (PCU) in patients previously treated with TAVI have been reported in small series (9). Against this background, the purpose of this retrospective multicenter study is to evaluate incidence, clinical indications, and feasibility of PCI performed after TAVI.
Objectives	1. Evaluate the incidence of PCI after TAVI 2. Evaluate the clinical indications for PCI after TAVI 3. Evaluate the technical feasibility of PCI in patients with prior TAVI 4. Evaluate in-hospital and long-term clinical outcomes in patients undergoing PCI after TAVI
Study Design	Retrospective, multicenter, international observational study
Inclusion Criteria	Any patient undergoing PCI after TAVI, irrespective of clinical indications and irrespective of whether planned or not at the time of TAVI
Exclusion Criteria	None
Data of Interest	See dedicated extraction sheet
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Steering Committee	TBD

GCP Statement	The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with ICH Good Clinical Practice as well as regulatory requirements
Confidentiality	This protocol is property of the principal investigators and may not – in full or in part – be passed on, reproduced, published or otherwise used without permission

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