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The FULL REVASC (Ffr-gUidance for complete non-culprit REVAS Cularization) Registry-based Randomized Clinical Trial

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Statement of the Problem: Complete revascularization in ST elevation myocardial infarction (STEMI) patients with multivessel disease has resulted in reduction in composite clinical endpoints in medium sized trials. Only one trial showed an effect on hard clinical endpoints, but the revascularization procedure was guided by angiographic evaluation of stenosis severity. Consequently, it is not clear how Fractional Flow Reserve (FFR)-guided percutaneous coronary intervention (PCI) affects hard clinical endpoints in STEMI. Methodology: The Ffr-gUidance for compLete non-cuLprit REVAS Cularization (FULL REVASC) – is a pragmatic, multicenter, international, registry-based randomized clinical trial designed to evaluate whether a strategy of FFR-guided complete revascularization of non-culprit lesions, reduces the combined primary endpoint of total mortality, non-fatal MI and unplanned revascularization. 1,545 patients were randomized to receive FFR-guided PCI during the index hospitalization or initial conservative management of non-culprit lesions. Findings: We found that in angio graphically severe non-culprit lesions of 90-99% severity, 1 in 5 of these lesions were re-classified as non-flow limiting by FFR. Considering lesions of intermediate severity (70-89%), half were re-classified as non-flow limiting by FFR. The study is event driven for an estimated follow-up of at least 2.75 years to detect a 9.9%/year>7.425%/year difference (HR=0.74 at 80% power (α = .05)) for the combined primary endpoint. Conclusion & Significance: This large randomized clinical trial is designed and powered to evaluate the effect of complete revascularization with FFR-guided PCI during index hospitalization on total mortality, non-fatal MI and unplanned revascularization following primary PCI in STEMI patients with multivessel disease. Enrollment completed in September 2019 and follow-up is ongoing.

Biography

Felix Böhm is a Consultant Interventional Cardiologist at the Karolinska University Hospital and is the Coordinating Principle Investigator for the FULL REVASC study. The executive committee for the study consists of experienced researchers within the field of Interventional Cardiology from several countries in Europe and Australia/New Zealand. The study is the first hybrid registry-based randomized clinical trial in Sweden; randomization and some of the endpoint follow-up is done within the SWEDEHEART registry in Sweden and through a separate website with endpoint follow-up through telephone calls and medical journal checks in other participating countries.

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