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Autor(en) des Beitrags:
Pontone, Gianluca; Patel, Manesh R; Hlatky, Mark A; Chiswell, Karen; Andreini, Daniele; Norgaard, Bjarne Linde; Byrne, Robert A; Curzen, Nick; Purcell, Ian; Gutberlet, Matthias; Rioufol, Gilles; Hink, Ulrich; Schuchlenz, Herwig W; Feuchtner, Gudrun; Martine; de Bruyne, Bernard; Rogers, Campbell; Douglas, Pamela S

Titel des Beitrags:
Rationale and design of the Prospective Longitudinal Trial of FFRCT: Outcome and Resource IMpacts study.

Abstract:
Fractional flow reserve (FFR) measured by coronary computed tomography angiography (FFRCT) has been validated against invasive FFR. However, there are no data on how the use of FFRCT affects patient care and outcomes. The aim of this study is to compare standard practice guided by usual care testing to FFRCT-guided management in symptomatic subjects with suspected coronary artery disease (CAD). In this prospective nonrandomized trial, symptomatic patients with suspected CAD will be enrolled in 2 consecutive cohorts: a usual care-guided pathway (cohort 1) and an FFRCT-guided pathway (cohort 2). Each cohort is divided into 2 groups according to whether noninvasive or invasive diagnostic testing was planned before enrollment. In all subjects, the patient's clinical team will review all diagnostic test results and determine a treatment strategy. A total sample size of 580 subjects will be enrolled and followed up for 12 months. The primary end point is the comparison of the percentage of patients with planned invasive testing who have a catheterization (invasive coronary angiography) within 90 days from
initial assessment, which does not show a significant stenosis (defined as coronary artery stenosis > 50% or invasive FFR <= 0.80). Secondary end points include the rate of invasive coronary angiography without obstructive CAD in those with planned noninvasive testing and, in all groups, noninferiority of resource use, quality of life, medical radiation exposure, and major adverse cardiac events up to 365 days of follow-up. The study compares clinical and economic outcomes based on diagnostic evaluation using FFRCT with that based on standard diagnostic strategies.