# Cost-effectiveness of adding a non-invasive acoustic rule-out test in the evaluation of patients with suspected stable angina pectoris. Design of the randomized multicenter FILTER-SCAD trial

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**Background:** Patients with suspected stable coronary artery disease (CAD) are selected for further non-invasive or invasive diagnostic tests depending on their pre-test probability (PTP) of obstructive CAD. However, the PTP, based on age, sex, and type of angina, has shown to grossly overestimate the likelihood of obstructive CAD. Consequently, the use of diagnostic tests has increased over the last decades despite a low diagnostic yield (6–7%). The CAD-score is a risk stratification score for obstructive CAD measured using a novel non-invasive acoustic device, and when added to PTP has shown excellent rule-out capabilities.

**Purpose:** To investigate if the addition of the CAD-score to a standard diagnostic examination is superior in terms of reducing overall number of diagnostic procedures and non-inferior in terms of safety as compared to a standard PTP-guided strategy when evaluating patients with suspected stable CAD.

**Methods:** The FILTER-SCAD trial is a randomized, controlled, multicenter trial expected to include 2000 subjects $\geq$30 years of age without known CAD referred for outpatient assessment for suspected CAD at 5 hospitals in Denmark and Sweden. First subject was randomized on October 22, 2019.

Subjects will be randomized 1:1 to either 1) a control group undergoing standard diagnostic examination (SDE) according to current guidelines, or 2) an intervention group undergoing SDE plus a CAD-score measurement, using permuted block randomization stratified by study site and PTP (very low vs. low-intermediate). Follow-up will be 12 months for a primary endpoint of cumulative number of diagnostic tests and a combined secondary safety endpoint of all-cause death, non-fatal myocardial infarction, unstable angina pectoris, heart failure, and ischemic stroke. Questionnaires assessing symptom severity, quality of life, life style measures, and medical treatment will be collected at baseline, 3 months, and 12 months after randomization.

The study is powered to detect superiority in terms of cumulative number of diagnostic tests with a power of 80% and a significance level of 0.05, and non-inferiority on the safety endpoint with a power of 90% and a significance level of 0.05. The study is conducted in compliance to the principles of the Declaration of Helsinki of the World Medical Association. ClinicalTrials.gov ID: NCT04121949.

**Results:** One study site is currently enrolling. Preliminary baseline data is available on the first 77 (44% males) enrolled patients (median age 61 years IQR (51–72) and PTP 22% IQR (13–38)) showing successful randomization with even distribution of baseline characteristic between the two groups including sex, age, and PTP.

**Perspectives:** The FILTER-SCAD trial will investigate whether it is feasible to reduce resource consumption without compromising safety in the outpatient assessment of patients with suspected CAD using a simple, non-invasive acoustic device. Enrollment and follow-up are expected to be completed spring 2022.