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Revascularization Choices Among Under-Represented Groups Evaluation (The RECHARGE Program)

Project Summary

Coronary artery disease (CAD), disease of the major blood vessels that supply the heart, is the most common cause of death in the United States. Revascularization, or opening, of diseased vessels can be achieved by percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG), and both procedures improve patients' length of life, symptoms and quality of life. More than one million patients in the United States alone undergo either PCI or CABG annually.

The PCI procedure is less invasive than the CABG surgery and entails a small puncture of a blood vessel in the groin or wrist to pass wires, catheters, and stents down the coronary artery to dilate and prop open each obstruction to improve cardiac blood flow. The CABG surgical procedure requires surgical opening of the chest cavity and a prolonged recovery period after the procedure. Current professional guidelines recommend that the decision to perform PCI or CABG be guided by patient preference as informed by a local heart team consisting of a team of heart specialists and surgeons, with consideration of the evidence that is available from previous studies. More than half of patients confronting this decision are women or a racial or ethnic minority, both of which are groups underrepresented in previous clinical studies which have mainly recruited Non-Hispanic White men. Thus, there is uncertainty as to whether PCI or CABG is the best treatment option for women and underrepresented minority patients.

The Revascularization CHoices Among underRepresented Groups Evaluation (RECHARGE) program overcomes existing controversies on participant selection and outcomes that are important to patients by explicitly enrolling women and underrepresented minorities in two separate trials (RECHARGE:Women and RECHARGE:Minorities). The RECHARGE program will focus on the outcomes that matter most to patients: living longer and living better. The RECHARGE program aims to compare length of life and quality of life for women and underrepresented minorities with CAD who are treated with PCI compared to CABG. The long-term objective is to provide robust patient-centered evidence to base treatment decisions on for revascularization of CAD in women and minorities. The two key innovations of the RECHARGE program are:

To provide a robust comparison of PCI vs CABG solely in women (RECHARGE:Women) and underrepresented minorities (RECHARGE:Minorities).
The specification of a patient-centered primary outcome (survival and quality of life), which differs from all prior trials that have often been driven by processes of care that do not adequately reflect long-term symptom burden and quality of life.

The RECHARGE program will be composed of two separate trials, one enrolling approximately 600 women (RECHARGE:Women) and the other approximately 600 Black and Hispanic patients (RECHARGE:Minorities). Patients will be randomly selected to undergo PCI or CABG.

The primary outcome measure will be a combination of death and overall quality of life, assessed using the 12-item Short Form Surveys (SF-12v2), designed for capturing the overall quality of life, at one, three, six, 12, 18, 24 and 36 months. The project team will compare PCI to CABG in both RECHARGE:Women and RECHARGE:Minorities. The most important secondary outcome will be the disease-specific quality of life (measured using the Seattle Angina Questionnaire Overall Summary score, which is specifically developed for patients with CAD). Additional secondary outcomes are generic quality-of-life outcomes assessed by the Patient-Reported Outcomes Measurement Information System (PROMIS) instruments; a combined outcome of major clinical events including death, stroke or heart attack; a combined outcome of death, stroke, heart attack or readmission to the hospital for any reason; and the individual components of the composite outcomes including cause-specific death, stroke, heart attack and cause-specific rehospitalizations (including the need to undergo a repeat revascularization procedure) reported at regular intervals during three-year follow-up. The outcome data will be collected using study-specific questionnaires and case report forms and stored electronically.

The RECHARGE trial has engaged patients, caregivers, health systems leaders and policy makers through a patient and stakeholder advisory board (PASAB). The PASAB has provided insight into all aspects of trial design, recruitment and retention for the feasibility phase and the full-scale trial.