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Clinical trial pursues best treatment options for asymptomatic carotid artery stenosis patients

The Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial (CREST-2) is a multi-center randomized clinical study to determine the best way to prevent strokes in people who have a high amount of blockage of their carotid artery but no stroke symptoms related to that blockage. UCLA's divisions of vascular surgery, neurology and cardiology are participating in the study.

Between one and three million Americans suffer from asymptomatic carotid artery stenosis (ACAS), a key stroke risk due to the accumulation of plaque (arteriosclerosis) that can remain without stroke warning signs for decades.

CREST-2 builds on data collected in an earlier CREST study that also focused on two surgical revascularization options to reopen the carotid arteries: carotid endarterectomy (CEA) — removal of plaque on the inside of the artery — and carotid artery stenting (CAS) or angioplasty — placement of a small expandable tube inside the artery. Results of the original CREST study, published in 2010, showed the two procedures to have good overall safety and efficacy.

Assessing strategies for patients at risk for stroke

"The crucial question to be answered by the CREST-2 clinical trial is whether it is still productive and appropriate to revascularize the carotid artery, either surgically or with stenting, in asymptomatic patients," says Wesley Moore, MD, professor and chief, emeritus, UCLA Division of Vascular Surgery and UCLA CREST-2 principal investigator. "Rapidly evolving advances in intense medical treatment (IMT) might obviate the need for the invasive procedures.

"The old paradigms for deciding the timing of revascularization need to be revisited to determine which strategy achieves the optimal stroke prevention rates," explains Dr. Moore. "We are actively recruiting trial candidates who will receive care from some of the nation's most highly regarded stroke specialists. If CREST-2 shows that IMT alone is not inferior to carotid endarterectomy or carotid stent/angioplasty plus IMT, then hundreds of thousands of patients will be spared invasive carotid intervention.

"CREST-2 will help physicians to make the choice precisely suiting each patient. The sooner this trial is completed, the better."

Dated research guides treatment

Current guidelines recommend revascularization in most patients with asymptomatic carotid stenosis. Yet intensive medical treatment (IMT) for ACAS was last tested in the early 1990s, so the most recent research evaluating medical therapy does not reflect improvements and refinements since that time.

Lifestyle and pharmacological advances including diet and exercise modifications and the emergence of statins, antiplatelet drugs and angiotensin-converting enzyme (ACE) inhibitors have substantially reduced stroke risk over the past 25 years, rendering much of the current stroke-prevention information nearly obsolete.

Major features of CREST-2

Consequently, a need exists for a new randomized trial to test whether contemporary IMT is an acceptable alternative to endarterectomy or stenting. Instead of comparing the two surgical interventions to each other, CREST-2 is divided into two arms, with one arm comparing IMT alone to IMT and CEA and the other comparing IMT alone to IMT and CAS.

The primary outcome measurements will be the number of deaths and strokes that occurred within 44 days of patient randomization and the incidence of new strokes in the study artery — the carotid artery with high-grade stenosis for which the patient was enrolled in the trial — for an average of four years afterward. Patient follow-ups will continue until at least two years after the last patient is randomized.

Cognitive testing will also be carried out at the time of randomization, during the course of the trial and on completion of the trial.

If CEA and/or CAS turn out to be more effective than IMT alone in prevention of stroke and maintenance of cognitive function in asymptomatic patients, then invasive carotid intervention will clearly be established as the preferred approach for the treatment of ACAS patients.

Participation in CREST-2

The study population includes people aged 35 years and older with high-grade ACAS. Both trial arms will randomize 600 asymptomatic patients to each group (IMT alone and IMT with intervention) for a total of approximately 2,400 study participants, all of whom have at least 70 percent blockage of one of their carotid arteries.

Modeling clinical practice, referring physicians will recommend appropriate revascularization — surgery or stenting — for each patient based on clinical testing and patient preference. Participants in each group will then be randomized to receive IMT alone or IMT plus revascularization.

UCLA is particularly well positioned to participate in CREST-2. The divisions of vascular surgery, neurology and cardiology have the technical expertise as well as the study infrastructure to carefully manage patients and to contribute meaningful information to the trial and the scientific community.

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crest2trial.org
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