

# Patients Benefit from Clinical Trials at ACC

Large, especially sophisticated specialty practices bring patients a benefit often only associated with university or teaching-hospital environments: treatment in clinical trials. Associated Cardiovascular Associates enrolls patients in an extensive list of research trials—in areas ranging from new cardiac drugs to innovations in treating heart-rhythm conditions to advances in interventional catheterization techniques.

“Clinical research is an important way to achieve cutting-edge care,” said Richard Perlman, MD, PhD, director of research at ACC. “We select trials with careful scrutiny, choosing those that can have the most benefit for patients and are the safest.”

*At ACC, investigative care adds to and complements standard care.*

All studies are FDA monitored and most are phase III trials of devices, agents or techniques nearing approval, or phase IV trials of advances newly in use. Most ACC clinical trials are in three areas:

- **Pharmaceutical research on new drugs coming to market**, including trials of new agents for acute MI, heart failure, atrial fibrillation, diabetes-related heart disease and hyperlipidemia.

Among current trials at ACC is the SOLID-TIMI (Stabilization of Plaques using Darapladib-Thrombolysis In Myocardial Infarction) study. Patients who have experienced unstable angina or MI due to coronary atherosclerosis are randomized to control or treatment with darapladib, a new class of medication that inhibits Lp-PLA<sub>2</sub>, an enzyme found in blood and plaque. Produced by inflammatory cells and associated



*Darius Sholevar, MD, meets with a patient participating in a clinical trial at ACC.*

with LDL, Lp-PLA<sub>2</sub> destabilizes plaque and is found in high concentration at sites of lesions that are likely to rupture and cause heart attack. This phase III study looks at cardiovascular events, such as a heart attack or stroke, when treatment is started within 30 days after acute coronary symptoms.

- **Electrophysiology studies**, including new pacemaker and defibrillator capabilities or uses.

Among these trials is the REFINE ICE study, which looks at whether use of defibrillators in patients with only mild or moderately decreased heart function is beneficial. ACC serves as one of 17 centers randomizing such patients to standard treatment plus ICD implantation.

“Until now, ICDs were considered only for patients with severely decreased heart function. Recommendations were ambiguous for those with lesser heart disease, and selection has been a difficult decision,” explained Dr. Perlman. “This study will determine if placing an ICD prophylactically in those patients delivers significant benefit.”

- **Interventional catheterization studies**, including new stent technology.

Most ACC staff members are sub- or principal investigators in the more than 20 trials currently active at the practice. Visits and interventions often carry no charge to patients when conducted under a trial. ACC’s six research coordinators hope to expand investigational care through the practice’s new relationship with Lourdes.

“What’s most impressive in the whole process are the patients who make the informed decision to volunteer for a clinical trial without having any way of knowing, of course, whether they will get a benefit from it or not,” said Donna Palazzo, administrative director of research at ACC. “They are among the millions each year who we admire for giving the gift of participation.”

■ To contact the ACC research program, call 856-673-1355.