

Cardiac Imaging Trial Launched

ACRIN 4701: The RESCUE Cardiology Trial Assesses Costs Related to Coronary CT Angiography and Nuclear Medicine Stress Test

By Martha L. Heckel, BA, ACRIN Protocol Associate II

In early 2011, ACRIN welcomed a new cardiology trial to its repertoire: ACRIN 4701, Randomized Evaluation of Patients with Stable Angina Comparing Utilization of Diagnostic Examinations, known as RESCUE.

The Research Question:

In comparison with traditional care using diagnostic nuclear medicine stress testing, can CCTA imaging studies of the heart reduce costs and revascularization procedures while appropriately diagnosing CAD and leading to safe and effective use of medical therapy and/or revascularization?

The Agency for Healthcare Research and Quality (AHRQ) is sponsoring this trial to determine if the clinical diagnostic pathway of coronary computed tomography angiography (CCTA) alone is cost-effective in comparison with traditional-care nuclear medicine stress testing—single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI)—possibly followed by invasive coronary angiography (ICA). ICA, an invasive

procedure often necessary for complete diagnosis following SPECT MPI, is routinely unnecessary after CCTA results are obtained.

ACRIN Cardiovascular Committee Chair and trial co-chair Pamela K. Woodard, MD (Washington University, St. Louis) explains, “Comparison of the effectiveness of CCTA and conventional angiography [SPECT MPI] in assessing patients at moderate risk of CAD [coronary artery disease] is a research priority highlighted in the 2009 Institute of Medicine’s Initial National Priorities for Comparative Effectiveness Research report. This trial holds significant promise to improve clinical care.”

While the ACRIN PA 4005 trial is evaluating diagnosis with CCTA in the emergency department environment, the ACRIN 4701 RESCUE trial will evaluate the use of diagnostic imaging among participants with stable angina—chest pain or discomfort typically associated with activity or stress. The trial is designed to randomize participants with stable angina symptoms to imaging diagnostic evaluation using either CCTA or SPECT MPI/ICA. Depending on the results of the diagnostic test, the participants may be exempt from treatment, be prescribed medical therapy, or go on to surgery/revascularization. “With traditional SPECT MPI, patients with a positive test for CAD will require ICA to determine if they can safely be treated with pharmacologic therapy and lifestyle intervention, also known as optimal medical therapy, or OMT; however, recent research suggests that CCTA has the potential to determine which patients can be treated with OMT,” says principal investigator Arthur Stillman, MD, PhD (Emory University, Atlanta).

The primary aim is to evaluate outcomes and, hypothetically, show no increase in major adverse cardiac

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Congratulations!

The research team at the Cardiac Study Center in Tacoma, WA enrolled the first patient onto the RESCUE trial Monday, May 23.

Meanwhile, competition ensues for ACRIN sites to become members of the “Rapid Ten” (see sidebar).

Rapid Ten for ACRIN 6690



You may have noticed the above logo on the “Participating Sites” pages of the ACRIN Web site. Starting with the ACRIN 6690 trial, ACRIN is recognizing sites that are among the first ten to complete all the activation requirements.

Below, we recognize the “Rapid Ten” sites for ACRIN 6690 trial. Many more sites have since activated the trial; our thanks to all for your hard work and dedication.

University of Alabama
Birmingham, AL

Mayo Clinic
Scottsdale, AZ

University of Southern California
Los Angeles, CA

Yale University
New Haven, CT

Lahey Clinic Inc.
Burlington, MA

University of Michigan
Ann Arbor, MI

Carolinas Medical Center
Charlotte, NC

University of Pennsylvania Medical Center
Philadelphia, PA

University of Texas Health Science Center
San Antonio, TX

University of Washington
Seattle, WA

ACRIN[™]
AMERICAN COLLEGE OF
RADIOLOGY
IMAGING NETWORK

11th Annual RA Education Session at ACRIN Fall Meeting

Wednesday September 29, 2010

This recap of the 11th annual RA Education Session, which took place at the Ritz Carlton in Pentagon City, comes just as plans are being finalized for the 12th such session to be held at the same location on Wednesday, September 21, 2011. For RAs who have yet to experience this day-long educational program, this serves as a good preview to the helpful variety of presentations in store for those attending this fall.

Thank you to all who attended and contributed to the 2010 meeting; they seem to get better and better every year. A major highlight was the midmorning focus group workshop in which groups of 15-20 attendees brainstormed ideas on how to tackle a particular study accrual challenge. Following highly interactive discussions, each group presented its challenge and recommendations in an at-large session held just before lunch. The focus group recommendations will be incorporated into the next RA Executive Committee paper.

Feedback from the accrual focus group workshop held during the 2010 Annual Meeting RA Education Session, along with all of the session slides, will be posted on the ACRIN RA Committee section of the ACRIN Web site (www.acrin.org/COMMITTEES/RESEARCHASSOCIATES.aspx).

Other highlights included the following presentations: “Super RA,” a definition of the RA role (Tracy Sitton-Petro); “Medical Imaging Radiation Exposure” (Mehdi Adineh, PhD); “How to Torture a Statistician” (Benjamin Herman, SM, Brown University); and “Critical Reading of Diagnostic Imaging Papers” (Constantine Gatsonis, MD, Brown University).

During the lunch break, ACRIN Chair Mitchell Schnall discussed the state of ACRIN and the valued contribution of RAs to its activities. He also presented the 5th annual Jo-Ann D’Amato Award of Excellence to Jennifer Encinas for her expertise and dedication to ACRIN’s mission at the University of Southern California. Chosen from a group of 7 nominees, Jennifer was nominated for her “unwavering courtesy, honesty, and responsibility,” her commitment to excellence, and her “tireless compassion and devotion” to study participants. This award continues to showcase the great work of ACRIN RAs while honoring the memory of a dear friend and colleague.

The RA Boot Camp, organized and presented by the RA Mentorship Subcommittee, took place during the afternoon. Monene Kamm, Martha Heckel, and Tracy Sitton-Petro

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Angel A. Loor, MA, Senior Manager (University of Miami Miller School of Medicine) presents the results of the working group that addressed accrual challenges related to the stage of disease of a study’s target population (left). Debra Hewing, MBA, BS (Washington University) presents the results of the working group that addressed issues related to clinical trial budgets (right) (St. Louis).

Tidbits

SoCRA Examination

ACRIN is once again pursuing the opportunity to host the Society of Clinical Research Associates (SoCRA) certification examination in conjunction with the ACRIN Annual Meeting. Broadcast e-mail notification will be distributed when all details are finalized. The examination date and time will be posted to the SoCRA Web site “Examination Schedule” table (www.socra.org/html/certific.htm). All questions related to examination requirements and registration should be directed to SoCRA.

Coming Soon!

REVISE IT is a new tool that will allow sites to revise their data (real time) via the ACRIN Web site instead of printing forms, making revisions on the forms, and sending form revisions to ACRIN for database corrections.

Friendly Reminders

RAs are asked to do the following:

- Notify ACRIN of staffing changes at your site.
- Do not share ACRIN passwords.
- Actively participate in and provide feedback regarding site conference calls.

The Networking and Publications Subcommittee would love to hear from you! Please feel free to share your ideas for newsletter topics and/or feedback by contacting Tina Taylor, CCRP at ttaylor@acr.org.

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Jennifer Encinas, BA, from the University of Southern California, receives the 2010 Jo-Ann D'Amato Award of Excellence for her expertise and dedication to ACRIN's mission. Jennifer was nominated for her undeviating courtesy, honesty, and responsibility supporting ACRIN trials, along with her commitment to excellence and her compassion and devotion to study participants.

spearheaded the camp, which is dedicated to providing research basics to those just starting out on ACRIN trials. Feedback from those who attended in 2010 was very positive, and we plan to continue offering this session from year to year to support our new RAs. The old-timers (experienced RAs) attended a separate session in which they were entertained and educated by Ben Herman and Dr. Gatsonis.

To finish off the day and provide RAs with an opportunity to discuss protocol-specific issues, the tradition of roundtable discussions was continued. During these informal breakout sessions, ACRIN project management, data management, imaging, and regulatory representatives were available to answer questions and provide support to RAs regarding the trials on which they were working.

We enjoy preparing this meeting for all of you and appreciate the feedback we received on the meeting evaluations. Please know that we keep your comments in mind as we plan each year's meeting. If you didn't complete an evaluation and have any suggestions for future meetings, please e-mail your suggestions to Lorna Beccaria at LornaB@ocsi.us.

Remember to register early for the 2011 RA Educational Session, as hotel rooms book up fast. We look forward to seeing many RAs, newcomers and long-timers alike, in September.

From ACRIN Data Mangement

New Procedure for Web-Entering ACRIN Multiple Occurring Forms Data

By Marcella Edmond-Bell
ACRIN Research Associate II

To minimize data entry errors and time spent Web-entering multiple occurring forms data, ACRIN has developed a new procedure that allows users to enter multiple instances of the multiple occurrence form without leaving the Web-entry screen.

In the past, when users Web-entered multiple occurring forms, the Web-entry program took them back to the data collection screen, where they had to re-select the multiple occurring form each time an additional record or row needed to be added. This process was time consuming, especially when more than one record (often more than 10) had to be Web-entered, and would also result in data entry errors. "New Row/Record" and "Complete Form" buttons have been added to the multiple occurring Web-entry screens, allowing users to enter multiple instances of a form without returning to the data collection screen and re-selecting the form for Web-entry.

The "Next Row/Record" button takes users to the next case record number (also known as instance, row, or sequence) of the form, which is an identical screen with identical elements. The data entered is submitted upon selection of the "Next Row/Record" button, and the confirmation e-mail is generated. This also allows users to skip the confirmation screen.

The "Complete Form" button works similarly to the "Submit" button but returns users to the data collection screen and out of the multiple-occurrence loop.

We hope you find the process easier and more efficient.

More Images from the 2010 RA Session



Ruth Holdener RT(R)(M)(CT), from Washington University in St Louis, leads the working group that addressed considerations for selecting trials that meet with success.



ACRIN data managers Glenna Gabrielli, BS, CCRP (left), and Stephanie Clabo, BS, CCRP, lend a hand at the registration desk for the RA Education Session.



Patricia Fugal, MS (left), and Svetlana Vassilleva, MD, both from Yale University, enjoying their meeting experience.

A Final Milestone for NLST

ACRIN extends a sincere “thank you” to all National Lung Screening Trial (NLST) coordinators, research associates, recruiters, data support personnel, and other site staff who played a significant role in the success of the NLST. So many dedicated site staff contributed to the NLST, which was conducted over an expansive 12-year period. Protocol development began in 1999, enrollment commenced in August 2002, screening was completed in February 2004, and follow-up data collection continued through December 2009. Successful completion of this trial required a Herculean effort from the site staff members who collected data from approximately 18,900 participants (on 131 cases report forms), covering imaging data, quality of life, and follow-up information for 5-8 years after enrollment to the trial. In addition, site staff collected death certificates and medical records, for cause of death verification and abstraction.

Initial results of the NLST, released in November 2010, concluded that screening with low-dose helical computed tomography (CT) can reduce lung cancer deaths in former and current heavy smokers aged 55-74 by 20%; the full results will be published in mid-2011. Thereafter, manuscripts that address the screening results, the effect of screening on quality of life, implications of the costs associated with screening, and numerous ancillary analyses of the large amount of data collected will be released over the next several years. It is expected that the NLST results will be a major influence in the development of public policy for lung cancer screening.

As NLST sites prepare records for long-term retention and for database closure in September 2011, they should know that ACRIN is extremely grateful for the significant contribution and commitment from each and every member of each site research team. What an extraordinary effort!

For more information about the NLST, visit www.cancer.gov/NLST/updates and www.acrin.org. Information on NLST-related scientific papers that describe the study and its results will be posted to the ACRIN Web site as such papers are published.

More Acronyms

CCOP - Community Clinical Oncology Program

COG - Children’s Operative Group

CPS - Cancer Prevention Study

CTSU - Clinical Trials Support Unit

DCP - Division of Cancer Prevention

DCTD - Division of Cancer Treatment and Diagnosis

ECOG - Eastern Cooperative Oncology Group

GOG - Gynecology Oncology Group

IPC - Institution Participants Committee

OEWG - Operations Efficiency Working Group

RTOG - Radiation Therapy Oncology Group

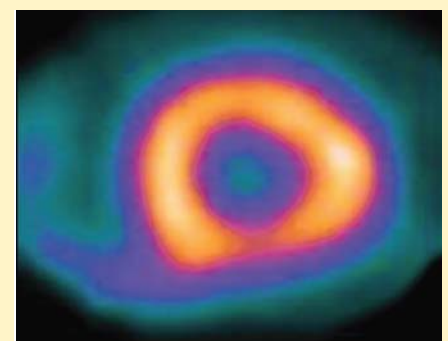
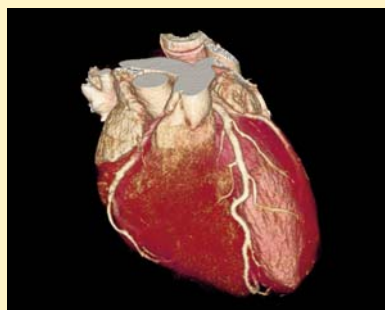
SWOG - Southwestern Oncology Group

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events (MACEs), defined as heart attack or cardiac-related death, or revascularization among the 2 study groups. Additional aims relate to the prognostic capabilities of CCTA, costs of diagnosis and subsequent care, and angina symptoms and self-reported health status among participants. Follow-up with the participants to determine cardiac-related care and care related to incidental findings will trigger medical record collection and abstraction for costs assessment. All occurrences of MACE and revascularization will be adjudicated by a team of cardiology experts.

The RESCUE trial will enroll 4300 participants at as many as 80 institutions internationally, including US Department of Veterans Affairs (VA) facilities.

If your institution is interested in more information, visit www.acrin.org/RESCUE_protocol.aspx or contact Cynthia Olson, ACRIN 4701 Project Manager, at colson@acr.org.



Images from cardiac CT angiography (CCTA) (left) and single-photon emission computerized tomography (SPECT) (above), which are both being performed in the RESCUE (ACRIN 4701) trial.

Oh! Regulatory

Adherence by RAs to the following guidelines and suggestions will help ensure that ACRIN clinical trials maintain ongoing regulatory compliance:

1. Keep in mind you can obtain the Data and Safety Monitoring Board (DSMB) minutes and reports (posted on the “Site Memos” section of the protocol-specific pages) on the ACRIN Web site.
2. Please ensure that ACRIN receives the most current versions of your regulatory documents (eg, updates to 1572s).
3. Timely institutional review board (IRB) and Federalwide Assurance (FWA) renewals are critical to prevent disruption of the clinical trial.
4. All IRB-approved revisions to the site-specific informed consent form (ICF) must be submitted to ACRIN.
5. All amendments received from ACRIN must be approved by the site IRB within 90 days of receipt.
6. Please notify the appropriate ACRIN protocol staff immediately of any scanner issues that affect participants and/or image quality.
7. Maintenance of source documents is critical to a successful monitoring and auditing review and, ultimately, to the success of the trial. Please be sure to develop processes for compiling and storing these documents.

QAC in the Know

The ACRIN Quality Assurance Committee (QAC) meets on a quarterly basis to review data submission and data quality across all ACRIN studies with regard to compliance with eligibility criteria, data received relative to data submission targets, completeness of data submission, and progress in resolving data queries. Percent compliance with study guidelines is reported for each category. Sites that drop below the 80% data quality score target are discussed at the QAC meeting and may receive noncompliance letters from the QAC chair. For more information about the QAC and site compliance standards, visit:

www.acrin.org/COMMITTEES/SUPPORT/QUALITYASSURANCE.aspx

IND Trial Drug Safety Reporting Guidelines

An Investigational New Drug (IND) trial is one conducted in conjunction with a request to the US Food and Drug Administration (FDA) for authorization to administer an investigational drug to humans before a marketing application for the drug has been approved. Trial safety data indicating that the drug will not expose subjects to unreasonable risk are necessary for its approval to enter a phase 1 clinical trial.

The following reminders are provided to assist sites in maintaining the data required for FDA IND approval:

1. Drug accountability is essential in conducting an IND trial. Please maintain accurate records for source verification. These documents must be available at the time of monitoring and audit.
2. For any investigational pharmaceutical agent, an adverse event (AE) assessment should be completed at 24 (\pm 4) hours after administration. Documentation is essential to ensure the safety and welfare of study participants.

Tips From the Mentors

By Tracy Sitton-Petro
Clinical Radiologists, Springfield, IL

Members of the Mentoring Subcommittee offer the following advice to RAs new to ACRIN or to clinical research:

1. When preparing for an audit visit, make sure your charts are well organized. Create a tabulated folder for all of your source documents, to allow auditors to easily locate laboratory results, imaging reports, etc.
2. To maximize participant accrual sources, check out your facility's tumor board meeting schedules. Most disease site subspecialties now conduct their own conferences. Try to attend these conferences on a weekly basis to make yourself known to the referring physicians and possibly pick up an eligible patient or two!

The ACRIN Research Associate Newsletter is developed in cooperation with the RA Executive Committee and ACRIN Headquarters and distributed to ACRIN's research community.

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Jo-Ann D'Amato AWARD OF EXCELLENCE



The ACRIN RA Executive Committee requests nominations for the sixth annual Jo-Ann D'Amato Award of Excellence. Established in 2006, the award recognizes an ACRIN research associate who best exemplifies the values that guided Jo-Ann and made her a valuable asset to ACRIN and a much beloved friend and family member.

Eligibility:

Award recipients must have been an ACRIN research associate for at least one year. In addition, they must be presently working on two or more ACRIN supported projects or devoting at least 50% of their time and effort to an ACRIN project.

Candidates should be nominated based on the following criteria:

- Professionalism in their role
- Performance as a research associate
- Compassion for patients
- Community service

Application and instructions for submission can be found on the ACRIN Web site: www.acrin.org by selecting the following links:

Committees→Research Associates→Materials→2011 Award Instructions and Application

Nominations must be received or postmarked by July 29, 2011

This award shall be presented on September 21, 2011 at the ACRIN Annual Meeting.