CABANA News
Catheter Ablation versus Antiarrhythmic Drug Therapy for Atrial Fibrillation

Retirements:

Janis (Jan) Haroldson, RN (Years of service 1998-2013)

The Mayo CABANA Team would like to express their most heartfelt appreciation to Jan Haroldson, RN, for all of her hard work and dedication of 15 years of service, within Dr. Packer’s research team. Jan has been involved with CABANA since the very 1st day of its inception. There is no one that can replace her within our hearts and she will be sincerely missed.

Happy Retirement & best wishes to you Jan.
From your CABANA Team Members!

Alice Mascette, MD (Years of service 2003-2013)

Alice M. Mascette, MD, retired from the National Heart, Lung, and Blood Institute in May 2013. Dr. Mascette joined NHLBI in 2003, after retiring from a 20-year career as an army cardiologist. At NHLBI, she served as Project Officer for the Occluded Artery Trial, the Heart Failure Clinical Research Network, and the CABANA trial, and had oversight of the initiation and/or management of two other large clinical trials networks, including the Resuscitation Outcomes Consortium. In her retirement, Alice will spend time enjoying her hobbies of Scrabble, rowing, hiking and choir singing. We wish Alice all the best and thank her for her 10 years of service to the NHLBI and the cardiology community, and most recently, her dedication and expert guidance in moving CABANA forward to where we are today.

REMARKABLE MILESTONE ACHIEVED!
Research Institute of Circulation Pathology
Novosibirsk, Russia
Dr. Eugeny Pokushalov

**Enrolls 100th Patient**

For more information check out our web site at www.cabanatrial.org
Kristi’s Korner

Kristi Monahan, RN, Project Director
CABANA Administration, Mayo Clinic

During the summer months we were all drawn to the warmth and sunshine as an inviting time for vacationing with family and friends. However, as part of the CABANA Team we must not lose site of the critical hour we are facing in regards to reaching our ultimate enrollment goal of 2200 patients for this trial (yes, we are decreasing the total number in the revised protocol). This means that we have recently passed the half-way mark of our goal and it is exciting to see a continued forward momentum. Let’s not “slow down”!

It’s exciting and worth mentioning that since the 1st of the year CABANA’s enrollment has increased from 980 to 1260, with an average monthly rate of (~35). This solidifies that we have definitely turned a “Korner” as far as enrollment is concerned but we really need to have each site adding ~1/month. We cannot stress enough the importance of continuing to increase our monthly enrollment for the ultimate success of this trial. The sooner we start the follow-up phase of the 2200th subject, the sooner we can report the results from all of your work.

In reflecting over CABANA thus far, there have been and will continue to be obstacles/challenges that are dealt with and overcome. In addressing the most current obstacles, you will see revisions that we hope will decrease the labor intensity for all sites.

- Protocol changes
  - Inclusion / Exclusion
  - Expansion of the follow-up windows
- eCRF changes
- Rhythm monitoring schedule change

Dr. Packer and I recognize the importance of our continued support and assistance to each member of the CABANA Family. Let us know how we can help!

Thank you for all of your diligence and hard work,

- Kristi

Mark Your Calendar!

- **NA Webcast**
  September 17th (Tues.)
  6-7 PM (CST)

- **NA Study Coordinator Teleconference**
  October 2nd (Wed.)
  8-9 AM & 3-4 PM (CST)

- **Boston AF Symposium (Orlando, FL)**
  January 9-11th (Thurs. - Sat.)
  CABANA Booth & Reception (details to follow)
CABANA Coordinating Center

Kerry L. Lee, PhD, Duke Clinical Research Institute

We consider it a great privilege at the Duke Clinical Research Institute (DCRI) to serve as the operations coordinating center for CABANA. A major part of our role in the past has consisted of recruiting clinical sites in North America, establishing contracts, providing training and support in order to help sites initiate patient enrollment. DCRI also provides training on the InForm electronic data entry/data management system, as well as follow-up support with monitoring and management of all data collected in the trial. We also manage the CABANA web site and provide the statistical leadership and support that is needed for all phases of the trial. To coordinate our activities with other components of the study organization, we participate in weekly conference calls with the CABANA leadership team at the Mayo Clinic, with representatives from the National Heart, Lung, and Blood Institute, and with the international CRO (World-wide Clinical Trials), which provides parallel operations support to CABANA centers located outside of North America.

A particularly key person at the DCRI Coordinating Center is Kathleen Moretz, RN, our capable project leader, who oversees a myriad of details concerning trial operations. Kathleen is ably supported by Lead CRAs Rita Weber, RN, and Sheri Ussery, RN. Our CRA team that works directly with the clinical sites consists of Ann Holmes, Tori Latiker, and Angela Belton, with assistance from Felicia Cathcart, Tinisha Turner, and Helen Harbett. The point person on InForm and issues of data management is Hoss Rostami, and the operational statistical activity is provided by Lauren Lindblad. Faculty-level leadership for the Coordinating Center is provided by Dr. Kerry Lee (statistical and data) and Dr. Tristram Bahnson (clinical). Other faculty, including Dr. Hussein Al-Khalidi and Dr. Kevin Anstrom, also provide important statistical support for the study.

The work of the coordinating center extends across all aspects of the study, including planning and design, project coordination, site management, data collection, data quality, data management, data analysis, and dissemination of results. In this important role, it is our desire to facilitate the research productivity of the entire CABANA ‘family’ and maximize the benefit and accomplishments from this large and important scientific undertaking. We desire to be helpful to all participating clinical centers in making CABANA a productive and successful effort for you. Please feel free to call or communicate with your CRAs or any of our Coordinating Center staff at any time if you have needs or questions where we may be able to help.

We greatly appreciate the opportunity to work with you and are grateful for the efforts you are making to support the successful completion of this important study.

- K. Lee
North American Spotlight: University of Calgary – Calgary, AB

The University of Calgary and Alberta Health Services form the collaborative Libin Cardiovascular Institute of Alberta, a multifaceted venture guiding clinical cardiology, research and education. The Libin Institute’s Cardiac Arrhythmia Program serves over 2.5 million people over a geographical area spanning three Canadian provinces and 300,000 square kilometers.

In 1978, Dr. George Wyse established the Cardiac Arrhythmia Program at Foothills Hospital. As the field of electrophysiology expanded to include invasive electrophysiology procedures, more physicians were recruited. Doctors Brent Mitchell and Anne Gillis joined the team between 1982 and 1985 and brought expertise in the pharmacology of arrhythmia management, cardiac pacing and invasive cardiac electrophysiology. The EP group now consists of 14 physicians and 30 Registered Nurses in clinical and research areas.

Over the next three decades, the Cardiac Arrhythmia Program has grown to include experts in the management of implantable cardiac devices for arrhythmia treatment, pediatric electrophysiology and cardiac genetics and stand-alone Atrial Fibrillation clinic.

The Libin Institute’s Cardiac Arrhythmia Program has extensive research experience including landmark trials such as SCD-HeFT, MUSTT, AVID, CIDS, CASH, CAST, C-TOP, AFFIRM, MADIT-CRT, RAFT, DINAMIT, POPS, POST I & II, VPS 1 & 2 & REFINE. We are now pleased to add CABANA to this list.

CABANA was initiated in May 2011 with Dr. George Veenhuyzen as our Primary Investigator. The Nurse Clinicians in our Atrial Fibrillation Clinic have been invaluable as they filter through the dozens of new referrals and identify potential CABANA subjects.

We anticipate even further CABANA success with the recent addition of a new hospital in the south of our sprawling city which houses a satellite AF clinic, providing more eyes and ears on the lookout for potential subjects.

Referrals to the CABANA trial have come from General Cardiologists, Electrophysiologists, and Family Physicians, even from patients themselves as they strive to control their own medical destiny and have found CABANA in the media.

Our Canadian health care system presents ongoing challenges and benefits to our population. While waiting lists and an inability to acquire specialized medical care are a reality, so too are the advantages of receiving comprehensive care via a centralized system regardless of personal finances.

Our patients are always very thankful for the attention afforded to them within the CABANA trial. In the words of one of our subjects:

“One year ago, after having many troubling A-Fib events I was invited to join CABANA. I found the study to be well organized and the doctor and nurse involved to be very informed and caring. The event monitor is interesting and has not been a bother. Medicomp is very prompt on their reminder phone calls to take a monthly ECG reading. Every few months the cardiologist sees me and I don’t even have to go on a waiting list, as I know friends who wait for months to see a doctor. The greatest plus of course, is that I am feeling much better and hopefully I am helping out in the study of Atrial Fibrillation!”

Our site is a proven leader in clinical care, research and education in Canada, training new physician scientists and allied health professionals in a progressive and academic center of excellence. We feel CABANA is an important study in the realm of AF treatment and look forward to being included in this potentially practice-changing process.
International Spotlight: Bakulev Scientific Center for Cardiovascular Surgery – Moscow, Russia

Being a part of the leading institution in Russia (Bakulev Scientific Center for Cardiovascular Surgery) our department of surgical treatment of tachyarrhythmia's aims to achieve the highest level of scientific and clinical work. Our participation in CABANA international research is an important and significant part of this goal.

In two EP laboratories we perform 900-1100 RFA-procedures annually, 400 of them are related to the treatment of atrial fibrillation (AF). Along with catheter ablation, we perform Cox-Maze 4 procedures (including the thoracoscopic surgery). We also implant more than 600 devices (including CRT-P and CRT-D) annually.

During catheter ablation, all patients undergo pulmonary vein isolation (PVI). Approximately 10% of them receive additional ablations of the CAFE-regions, projections of GP or linear lesions.

Participating in the CABANA trial is a great opportunity for us to collaborate with physicians and researchers all over the world, including leaders in the field of AF treatment, and to be among those who find the answer to the question - which is more preferable, more effective and safer in patients with AF – medication or catheter ablation.

Did You Know?

September is A-Fib Awareness Month