

## Arrhythmia Drug and Device Research Studies

Each year, hundreds of patients are treated by the Heart Center's Arrhythmia specialists. Arrhythmias, the abnormal electrical activity or the abnormal rate of muscle contractions in the heart, can make the heart beat too fast or too slow, and may be regular or irregular.

The Cardiologists and Electrophysiologists at the Lankenau Medical Center and Bryn Mawr Hospital participate in many multi-center clinical trials which evaluate the efficacy and safety of new drugs, devices and leads used to diagnose and treat arrhythmias and improve quality of life by reducing and/or eliminating the number of arrhythmic episodes. Patients with rhythm disorders can be evaluated for appropriate diagnostic testing and therapeutic treatments. Certain types of abnormal heart rhythms can be treated and cured with catheter ablation.

Our Electrophysiologists perform ablations for atrial fibrillation, atrial flutter and other supraventricular tachycardia's as well as ventricular arrhythmias like ventricular tachycardia.

<b>Arrhythmia</b>	Atrial Fibrillation
<b>Study Title</b>	Catheter Ablation Versus Anti-arrhythmic Drug Therapy for Atrial Fibrillation Trial - <b>CABANA</b>
<b>Sponsor</b>	Mayo Clinic <b>Collaborators:</b> NHLBI, DUKE University, St. Jude Medical & Biosense Webster, Inc
<b>Purpose</b>	The <b>CABANA</b> Trial has the overall goal of establishing the appropriate roles for medical and ablative intervention for atrial fibrillation (AF). The <b>CABANA</b> Trial is designed to test the hypothesis that the treatment strategy of left atrial catheter ablation for the purpose of eliminating atrial fibrillation (AF) will be superior to current state-of-the-art therapy with either rate control or rhythm control drugs for reducing total mortality in patients with untreated or incompletely treated AF.

<b>Indication</b>	Atrial Fibrillation
<b>Study Title</b>	A Multi-center, Parallel-group, Double-blind, Placebo-controlled, Randomized, Ascending Dose Trial to Determine the Safety, Tolerability, Pharmacokinetics and Efficacy of Intravenous Infusions of OPC-108459 Administered to Subjects with Paroxysmal and Persistent Atrial Fibrillation - <b>CADENCE</b>
<b>Sponsor</b>	Otsuka Pharmaceutical
<b>Purpose</b>	Rapid conversion of paroxysmal and persistent atrial fibrillation to normal sinus rhythm.

<b>Indication</b>	Atrial Fibrillation
<b>Study Title</b>	<b>REVEAL AF</b>
<b>Sponsor</b>	Medtronic Inc.
<b>Purpose</b>	The purpose of the study is to evaluate the incidence of atrial fibrillation (AF) in patients that are suspected to be at high risk of having AF. An implantable cardiac monitor will be utilized in the evaluation of AF.

<b>Indication</b>	Paroxysmal Atrial Fibrillation
<b>Study Title</b>	CARTO® 3 System and Real Time Intracardiac Ultrasound for Ablation of Drug Refractory Recurrent Symptomatic Paroxysmal AF: Acute Procedural Outcomes Study – <b>CARTO 3</b>
<b>Sponsor</b>	Biosense Webster Inc.
<b>Purpose</b>	The purpose of the study is to measure “real world” acute procedural outcomes associated with performing an ablation of drug refractory recurrent symptomatic paroxysmal AF using the CARTO® 3 System and real time intracardiac ultrasound to determine correlates for procedure efficiency and safety.

<b>Indication</b>	Abnormal EKG
<b>Study Title</b>	<b>Sudden Death Prevention Study</b> to Identifying ECG markers in the early stage of ARVD (Arrhythmogenic Right Ventricular Dysplasia)
<b>Sponsor</b>	American Heart Association
<b>Purpose</b>	Purpose is to detect ECG markers in early stage ARVD to improve the clinical diagnosis and help identify ARVD in its early stage for the prevention of sudden death in young people with the disease.

<b>Indication</b>	Lead study
<b>Study Title</b>	Longitudinal Surveillance Registry of the ACUITY Spiral Lead - <b>ACUITY Spiral</b>
<b>Sponsor</b>	Boston Scientific
<b>Purpose</b>	The primary purpose of this study is to evaluate the long-term reliability and clinical performance of the ACUITY Spiral lead. Product status information, related events and withdrawal data will be collected and the lead will be evaluated by a chronic LV-related complication-free rate over a 5 year follow-up period.

<b>Indication</b>	Lead study
<b>Study Title</b>	Attain Performa Quadripolar Lead Clinical Study – <b>ATTAIN Lead</b>
<b>Sponsor</b>	Medtronic Inc.
<b>Purpose</b>	The purpose of this clinical study is to evaluate the post implant safety and efficacy of the Medtronic Attain Performa Quadripolar Model 4298, Model 4398, and Model 4598 Left Ventricular (LV) leads.

<b>Arrhythmia</b>	Ventricular Arrhythmias
<b>Study Title</b>	Late Sodium Current Blockade in High-Risk ICD Patients: Ranolazine ICD Trial - <b>RAID</b>
<b>Sponsor</b>	University of Rochester
<b>Purpose</b>	The purpose is to determine whether ranolazine administration will decrease the likelihood of a composite arrhythmia endpoint consisting of ventricular tachycardia or ventricular fibrillation (VT/VF) requiring ATP therapy, ICD shocks, or death.

<b>Indication</b>	Heart Failure and Bi-ventricular ICD implant
<b>Study Title</b>	Effect of Optimizing the V-V Interval on Left Ventricular Contractility in Cardiac Resynchronization Therapy Study - <b>EVOLVE</b>
<b>Sponsor</b>	St. Jude Medical
<b>Purpose</b>	Patients who have a clinical indication for a bi-ventricular ICD may participate in this 6 month physician initiated trial.

<b>Arrhythmia</b>	Heart Failure, Ischemic or non-ischemic cardiomyopathy
<b>Study Title</b>	Left Atrial Pressure Monitoring to Optimize heart Failure Therapy - <b>LAPTOP</b>
<b>Sponsor</b>	St. Jude Medical

<b>Purpose</b>	The purpose of this trial is to evaluate the safety and clinical effectiveness of the LAP (left atrial pressure) Monitoring Systems and its effect on heart failure related events.
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<b>Indication</b>	Heart Failure, ischemic or non-ischemic cardiomyopathy and decreased left ventricular ejection fraction
<b>Study Title</b>	Optimizing the Left Ventricular Contractility in Cardiac resynchronization Therapy using a Doppler Wire - <b>CARE</b>
<b>Sponsor</b>	Boston Scientific
<b>Purpose</b>	The purpose of this study is to determine if optimal lead placement will result in improved functional patient response to Cardiac Resynchronization Therapy.

For additional information on these studies and other clinical trials, contact the Main Line Health Heart Center at 484-476-3030 or

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