

Sentara Cardiovascular Research Institute

Clinical Trials currently open to enrollment at Sentara Cardiovascular Research Institute:

Heart Failure/Electrophysiology Studies

Block HF

To assess whether biventricular pacing can slow the progression of heart failure in people with mild to moderate heart failure symptoms and the need for a pacemaker.

<http://www.clinicaltrials.gov/ct/show/NCT00267098?order=1>

Principal Investigator: John M. Herre, MD

For Information Contact: Linette Klevan, RN, BS at 757-388-2425 or via email:

lrklevan@sentara.com

Protect AF

This is a multi-center, prospective, randomized study, stratified by center, comparing the WATCHMAN device to long term warfarin therapy, demonstrating that the treatment arm is non-inferior to the control arm. <http://www.clinicaltrials.gov/ct/show/NCT00129545?order=1>

Principal Investigator: Paul Mahoney, MD

For Information Contact: Denise Karch, RN, BSN at 757-388-5408 or via email:

dxkarch@sentara.com

MADIT CRT

The MADIT-CRT trial is designed to determine if combined implantable cardiac defibrillator (ICD)-cardiac resynchronization therapy (CRT-D) will reduce the risk of mortality and heart failure (HF) events by approximately 25%, in subjects who are in New York Heart Association (NYHA) functional Class II with non-ischemic or ischemic cardiomyopathy and subjects who are in NYHA functional Class I with ischemic cardiomyopathy, left ventricular dysfunction (ejection fraction [EF] < or = 0.30), and prolonged intraventricular conduction (QRS duration > or = 130 ms).

<http://www.clinicaltrials.gov/ct/show/NCT00180271?order=1>

Principal Investigator: John Onufer, MD

For Information Contact: Denise Karch, RN, BSN at 757-388-5408 or via email:

dxkarch@sentara.com

Partners HF

The purpose of this study is to determine the value of diagnostic data obtained from Medtronic implantable cardioverter defibrillators (ICDs) with cardiac resynchronization therapy (CRT) to evaluate cardiovascular and heart failure related adverse events and health care utilization.

<http://www.clinicaltrials.gov/ct/show/NCT00279955?order=1>

Principal Investigator: Jaime Murillo, MD

For Information Contact: Linette Klevan, RN, BS at 757-388-2425 or via email:

lrklevan@sentara.com

MIBG-DePaul

The study is designed to study the utility of 123I-mIBG as a diagnostic imaging agent to predict cardiac outcome in subjects with heart failure and in comparison to subjects without cardiovascular disease. <http://www.clinicaltrials.gov/ct/show/NCT00126425?order=1>

Principal Investigator: Jaime Murillo, MD

For Information Contact: Linette Klevan, RN, BS at 757-388-2425 or via email:
lrklevan@sentara.com

MIBG-SNGH

The study is designed to study the utility of 123I-mIBG as a diagnostic imaging agent to predict cardiac outcome in subjects with heart failure and in comparison to subjects without cardiovascular disease. <http://www.clinicaltrials.gov/ct/show/NCT00126425?order=1>

Principal Investigator: John M. Herre, MD
For Information, Contact: Kathy Barackman, RN, MSN, CCRC at 757-388-3876 or via email:
kmbarack@sentara.com

Response HF

To evaluate the benefit of interventricular (V-V) delay optimization in reducing the non-responder rate in patients with CRT-D devices. <http://www.clinicaltrials.gov/ct/show/NCT00187200?order=1>

Principal Investigator: Allen Ciuffo, MD
For Information, Contact: Kathy Barackman, RN, MSN, CCRC at 757-388-3876 or via email:
kmbarack@sentara.com

Pegasus

Will look at different pacing modes, and how these modes affect quality of life.
<http://www.clinicaltrials.gov/ct/show/NCT00146848?order=1>

Principal Investigator: Robert Bernstein, MD
For Information, Contact: Kathy Barackman, RN, MSN, CCRC at 757-388-3876 or via email:
kmbarack@sentara.com

Esteem

This is a feasibility acute and chronic study of symptomatic heart failure patients with QRS duration <120ms, evidence of ventricular mechanical dyssynchrony, indicated for an ICD. The purpose of the study is to identify patients who will benefit from CRT.

Principal Investigator: John M. Herre, MD
For Information, Contact: Kathy Barackman, RN, MSN, CCRC at 757-388-3876 or via email:
kmbarack@sentara.com

Tele HF

Randomized, controlled trial that will compare outcomes in heart failure patients who receive daily telemonitoring and education with the Pharos Tel-Assurance system with those who receive usual care.

Principal Investigator: Jaime Murillo, MD
For Information, Contact: Amy Kanter, RN, BSN at 757-388-2812 or via email:
atkanter@sentara.com

Freedom

The objective of this study is to demonstrate that frequent atrio-ventricular (AV/PV) and inter-ventricular (V-V) delay optimization using QuickOpt in patients with CRT-D device results in improved clinical response over standard of care (i.e. empiric programming or one-time optimization using any non-IEGM optimization methods).
<http://www.clinicaltrials.gov/ct/show/NCT00418314?order=2>

Principal Investigator: John M. Herre, MD

For Information, Contact: Kathy Barackman, RN, MSN, CCRC at 757-388-3876 or via email:
kmbarack@sentara.com

ProRhythm

The purpose of this study is to determine if the HIFU Pulmonary Vein Ablation System is effective in the treatment of paroxysmal Atrial Fibrillation compared to the control of best medical therapy with FDA approved antiarrhythmic drugs.

<http://www.clinicaltrials.gov/ct/show/NCT00392106?order=2>

Principal Investigator: John Onufer, MD

For Information Contact: Denise Karch, RN, BSN at 757-388-5408 or via email:

dxkarch@sentara.com

Chronicle

To evaluate the safety of the Chronicle ICD system to assess the impact of the Chronicle based Patient Management Strategies on evaluating heart failure related events.

Principal Investigator: Jaime Murillo, MD

For Information Contact: Linette Klevan, RN, BS at 757-388-2425 or via email:

lrklevan@sentara.com

Reduce

Prospective, randomized study to determine if patients implanted with a St Jude ICD will benefit by using Autointrinsic Conduction Search rather than only a programmed AV/PV delay. This study will compare the 2 methods of programming with respect to intrinsic activity.

Principal Investigator: Robert Bernstein, MD

For Information, Contact: Kathy Barackman, RN, MSN, CCRC at 757-388-3876 or via email:

kmbarack@sentara.com

TOPCAT

The purpose of this study is to evaluate the effectiveness of aldosterone antagonist therapy in reducing all cause mortality in patients who have heart failure with preserved systolic function.

<http://www.clinicaltrials.gov/ct/show/NCT00094302?order=1>

Principal Investigator: John M. Herre, MD

For Information, Contact: Kathy Barackman, RN, MSN, CCRC at 757-388-3876 or via email:

kmbarack@sentara.com

Risk Stratification Madit II

A study to evaluate the predictive value of a multivariate model consisting of prespecified clinical and ECG parameters for predicting arrhythmic events in MADIT II type post-infarct patients with severe LV dysfunction and to develop a multivariate risk-stratification model and risk scoring algorithm that will enable an ordering of patients who may benefit most, and benefit least from ICD therapy.

Principal Investigator: John Onufer, MD

For Information Contact: Denise Karch, RN, BSN at 757-388-5408 or via email:

dxkarch@sentara.com

DSM VT

To assess the feasibility of using dynamic substrate mapping to guide ablation of ischemic ventricular tachycardia.

Principal Investigator: John Onufer, MD

For Information Contact: Denise Karch, RN, BSN at 757-388-5408 or via email:
dxkarch@sentara.com

Catheterization Laboratory Studies

SYNTAX

The SYNTAX trial is designed to determine the best treatment for patients with complex coronary disease (blocked or narrowed arteries in both the right and left sides of the heart) by randomizing patients to receive either percutaneous coronary intervention (PCI) with polymer-based paclitaxel-eluting TAXUS stents or to coronary artery bypass surgery (CABG).

<http://www.clinicaltrials.gov/ct/show/NCT00114972?order=1>

Principal Investigators: Ronald Stine, MD and Hormoz Azar, MD

For Information, Contact: Roe Mulvihill, RN, MN at 757-388-3529 or via email:
rbumulvih@sentara.com

CARS Registry

The primary objective of the study is to determine whether the STARFlex® septal closure system will safely and effectively prevent a recurrent embolic stroke/transient ischemic attack and mortality in patients with a PFO and to demonstrate superiority of the STARFlex® device compared to best medical therapy. <http://www.clinicaltrials.gov/ct/show/NCT00201461?order=1>

Principal Investigator: Paul Mahoney, MD

For Information, Contact: Melinda Bullivant, RN, MSN at 757-388-4024 or via email:
mmbulliv@sentara.com

Premium

The Purpose of this study is to evaluate the impact of percutaneous closure of a patent foramen ovale (a hole in the heart), using the AMPLATZER PFO Occluder, on the incidence of migraine headaches. <http://www.clinicaltrials.gov/ct/show/NCT00355056?order=1>

Principal Investigators: Drs. Vance/Lewis (CHKD) and Drs. Eich/Mahoney (SNGH)

For Information, Contact: Melinda Bullivant, RN, MSN at 757-388-4024 or via email:
mmbulliv@sentara.com

Triumph

A registry of MI patients looking at underlying disparities in acute MI patient's health status over 12 months.

Principal Investigator: John Brush, MD

For Information, Contact: Melinda Bullivant, RN, MSN at 757-388-4024 or via email:
mmbulliv@sentara.com

Champion PCI

The primary objective of this study is to demonstrate that the efficacy of cangrelor is superior, or at least non-inferior, to that of clopidogrel in subjects requiring PCI.

<http://www.clinicaltrials.gov/ct/show/NCT00305162?order=2>

Principal Investigator: Paul Mahoney, MD

For Information, Contact: Kate Matzgannis, RN, BSN at 757-388-2262 or via email:
jkmatzga@sentara.com

Champion Platform

The primary objective of this study is to demonstrate that the efficacy of cangrelor (combined with usual care) is superior to that of usual care, in subjects requiring percutaneous coronary intervention (PCI) as measured by a composite of all-cause mortality, myocardial infarction (MI), and ischemia-driven revascularization (IDR).

<http://www.clinicaltrials.gov/ct/show/NCT00385138?order=1>

Principal Investigator: Paul Mahoney, MD

For Information, Contact: Kate Matzgannis, RN, BSN at 757-388-2262 or via email:
jkmatzga@sentara.com

ATLAS

The purpose of this study is to evaluate the safety of rivaroxaban in subjects with recent acute coronary syndrome (ACS) and to assess the ability of rivaroxaban to reduce the rate of important clinical events in those patients. <http://www.clinicaltrials.gov/ct/show/NCT00402597?order=2>

Principal Investigator: Alan K. Banks, MD

For Information, Contact: Roe Mulvihill, RN, MN at 757-388-3529 or via email:
rbumulvih@sentara.com

Rocket AF

The purpose of this study is to demonstrate that the efficacy and safety of 20 mg once daily rivaroxaban in preventing thromboembolic events in subjects with atrial fibrillation not related to mitral valve stenosis. Subjects with moderate renal impairment at screening (defined as calculated creatinine clearance between 30 and 49 ml/min inclusive) will receive a dose adaptation to rivaroxaban 15 mg once daily.

<http://www.clinicaltrials.gov/ct/show/NCT00403767?order=1>

Principal Investigators: Ronald Stine, MD

For Information, Contact: Roe Mulvihill, RN, MN at 757-388-3529 or via email:
rbumulvih@sentara.com

JoStent HDE

Humanitarian Device Exemption for coronary stent graft used in coronary artery dissection.

Principal Investigator: All Physicians

For Information, Contact: Roe Mulvihill, RN, MN at 757-388-3529 or via email:
rbumulvih@sentara.com

Cardiac Surgery Studies

Restore-SR

To determine the safety and effectiveness of the Atricure Bipolar System during surgery for Afib.

Principal Investigator: Jeffrey Rich, MD

For Information, Contact: Laura Pine, RN, BSN, CCRC at 757-388-2732 or via email:
ljpine@sentara.com or Michelle Collier, RN, BSN at 757-388-7511 or via email:
mlcollie@sentara.com

POINT

To determine if increased magnesium levels prevents abnormal brain function after heart surgery.

Principal Investigator: David Schinderle, MD

For Information, Contact: Laura Pine, RN, BSN, CCRC at 757-388-2732 or via email:

ljpine@sentara.com or Michelle Collier, RN, BSN at 757-388-7511 or via email:

mlcollie@sentara.com

HeartMate II

The purpose of this study is to determine the safety and effectiveness of the Thoratec HeartMate II Left Ventricular Assist System (LVAS) as a bridge to cardiac transplantation in end-stage heart failure patients who are listed for cardiac transplant but are at imminent risk of dying.

<http://www.clinicaltrials.gov/ct/show/NCT00121472?order=2>

Principal Investigator: Jeffrey Rich, MD

For Information, Contact: Laura Pine, RN, BSN, CCRC at 757-388-2732 or via email:

ljpine@sentara.com or Michelle Collier, RN, BSN at 757-388-7511 or via email:

mlcollie@sentara.com

Stich

This study will compare medical therapy with coronary bypass surgery and/or surgical ventricular restoration for patients with congestive heart failure and coronary artery disease (CAD).

<http://www.clinicaltrials.gov/ct/show/NCT00023595?order=2>

Principal Investigator: Glenn Barnhart, MD

For Information, Contact: Laura Pine, RN, BSN, CCRC at 757-388-2732 or via email:

ljpine@sentara.com or Michelle Collier, RN, BSN at 757-388-7511 or via email:

mlcollie@sentara.com

Factor VII

The trial is planned to investigate the safety and efficacy of NovoSeven® in the management of post-operative bleeding in patients following cardiac surgery.

<http://www.clinicaltrials.gov/ct/show/NCT00154427?order=5>

Principal Investigator: Scott Ross, MD

For Information, Contact: Michelle Collier, RN, BSN at 757-388-7511 or via email:

mlcollie@sentara.com or Laura Pine, RN, BSN, CCRC at 757-388-2732 or via email:

ljpine@sentara.com

PROACT

Various patient groups with the On-X Valve can be maintained safely on lower doses of blood thinner (Coumadin®) or on antiplatelet drugs (aspirin/Plavix®) only rather than the standard dose of Coumadin and aspirin presently recommended by ACC/AHA or ACCP professional societies.

<http://www.clinicaltrials.gov/ct/show/NCT00291525?order=2>

Principal Investigators: Hormoz Azar, MD

For Information, Contact: Michelle Collier, RN, BSN at 757-388-7511 or via email:

mlcollie@sentara.com or Laura Pine, RN, BSN, CCRC at 757-388-2732 or via email:

ljpine@sentara.com

Mend CABG II

The purpose of this study is to determine the effect of MC-1 on the combined incidence of cardiovascular death and nonfatal myocardial infarction (MI) up to and including 30 days following coronary artery bypass graft surgery compared with placebo.

<http://www.clinicaltrials.gov/ct/show/NCT00402506?order=1>

Principal Investigator: Jeffrey Rich, MD

For Information, Contact: Laura Pine, RN, BSN, CCRC at 757-388-2732 or via email: ljpine@sentara.com or Michelle Collier, RN, BSN at 757-388-7511 or via email: mlcollie@sentara.com

BIOCOR

Post-Approval Study of the St Jude Medical Biocor and Biocor Supra Valves.

Principal Investigator: Glenn Barnhart, MD

For Information, Contact: Laura Pine, RN, BSN, CCRC at 757-388-2732 or via email: ljpine@sentara.com or Michelle Collier, RN, BSN at 757-388-7511 or via email: mlcollie@sentara.com

CTRD

A research database on adult cardiac transplant patients.

Principal Investigator: John M. Herre, MD

For Information, Contact: Laura Pine, RN, BSN, CCRC at 757-388-2732 or via email: ljpine@sentara.com or Michelle Collier, RN, BSN at 757-388-7511 or via email: mlcollie@sentara.com