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BayCare Cardiovascular Service Line Research

BayCare

2018 C.A.S.E.
Cardiovascular, Arrhythmia, Surgery and Endovascular
SYMPOSIUM

Clinical Research Team

Centralized Services

- Study Selection Process
- Contracts, Budgets
- Institutional Review Board Submissions

Centralized management

Four Members of the Administrative Team including finance and regulatory support

Local Staff

Four Coordinators at Morton Plant
Two Coordinators at St. Joseph's
One Coordinator at Mease Countryside, North Bay and Winter Haven

Over 200 patients participating in 20 enrolling studies and over 250 patients in follow up studies.

MILESTONES

St. Joseph's is beginning our first Phase 1 Study ArcticLine for recurrent atrial fibrillation

Morton Plant is the third highest enrolling site in the country for the DREAM STUDY: *A Randomized, Sham–procedure–controlled Study of Allogeneic Mesenchymal Precursor Cells (rexlemestrocel-L) in Patients with Chronic Heart Failure Due to Left Ventricular Systolic Dysfunction*

Morton Plant has consented the highest number of patients in the CardiAMP Study: A *Randomized Pivotal Trial of Autologous Bone Marrow Mononuclear Cells in Patients with Post Myocardial Infarction Heart Failure*

Morton Plant and North Bay BMG Cardiology participated in the landmark Compass trial Rivaroxaban 2.5 bid + ASA which showed a significant reduction in MACE in patients with chronic CAD or PVD compared to ASA alone

Cardiovascular Clinical Research

Enrolling:	MPH	MCS	NB	SJH	WHH
ADAPT RESPONSE	X	X			
APOLLO	X				
CALM 2				X	
CARDIAMP	X				
CONNECT HF				X	X
ECLIPSE				X	
EMPEROR (2)		X			
EVOLUT	X				
NSTEMI	X			X	
PIONEER					X
PORTICO	X				
PPP/SLS/PSR	X	X			
REFLECT	X				
REX REVEAL				X	
SMART CRT					X
STOP AF	?			X	
TEVA	X			X	
VICTORIA	X	X		X	
XIENCE 90	X	X	X		

CHF AND STEM TRIALS

LESLIE MILLER, MD
Medical Director,
Heart Function Clinic at Morton Plant Hospital

STEM CELL TRIALS

TEVA –DREAM: ***A Double-blind, Randomized, Sham–procedure–controlled, Parallel-group Efficacy and Safety Study of Allogeneic Mesenchymal Precursor Cells (rexlemestrocel-L) in Patients with Chronic Heart Failure Due to Left Ventricular Systolic Dysfunction of Either Ischemic or Nonischemic Etiology***

CardiAMP: ***Randomized Controlled Pivotal Trial of Autologous Bone Marrow Mononuclear Cells Using the CardiAMP Cell Therapy system in Patients with Post Myocardial Infarction Heart Failure***

NSTEMI: ***A double-blind, sham-controlled clinical study to evaluate the safety and feasibility of AMI MultiStem therapy in subjects who have had a heart attack (Non-ST elevation MI)***

CONGESTIVE HEART FAILURE TRIALS

VICTORIA : *A randomized parallel-group, placebo-controlled, double-blind, event driven, multi-center pivotal phase III clinical outcome trial of efficacy and safety of the oral sGC stimulator Vericiguat in subjects with heart failure with reduced ejection fraction (HFrEF)*

EMPEROR Trials : *Phase III randomized, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic heart failure with either reduced (HFrEF) or preserved (HRpEF)ejection fraction*

CONNECT HF: *A large-scale, pragmatic, cluster-randomized clinical trial to evaluate the effect of 2 quality improvement (QI) initiatives compared with usual care on heart failure (HF) outcomes and HF quality of care metrics in the year following discharge for participants hospitalized with acute HF and reduced ejection fraction (EF).*

AdaptResponse: *A prospective, randomized, controlled, interventional, single-blinded, multi-center, post-market, global Cardiac Resynchronization Therapy (CRT) in heart failure (HF) clinical study*

SMART CRT : *Strategic Management to Optimize Response to Cardiac Resynchronization Therapy*

Clearwater Cardiovascular Consultants

Practice Based Clinical Research Site

Investigator Bernardo Stein, M.D.

BayCare

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SYMPOSIUM

Clearwater Cardiovascular Consultants Clinical Research Site

Research Site since 1991

> 150 Drug, Device and Registry Sponsored Trials

> 5000 patient/subjects enrolled

CCC Research Team:

- 21 Physician Investigators
- 7 Clinical Research Coordinators
- Director, Regulatory Coordinator & several Research Assistants

Research Steering Committee

- 7 Physicians & Director meet every 2-3 months

Clearwater Cardiovascular Consultants Clinical Research Site

Subject Visits conducted at

3 CCC Clinics in Clearwater, Largo & Safety Harbor & CCC Cath Lab

Morton Plant Hospital & Mease Countryside Hospital

Current Study Portfolio

Enrolling	16
Follow Up	14
Startup / Closeout	5 / 7

Top enroller in many Global Trials

Twilight *Mount Sinai & Astra Zeneca*

Evolve Short DAPT *Boston Scientific*

Absorb III & IV *Abbott Vascular*

Wrap It *Medtronic*

Clearwater Cardiovascular Consultants Clinical Research Site

List of Currently Enrolling Studies

Aegis II	Acute ACS	Post ACS infusion CSL 112_3001 or placebo x 4 to reduce future CV events.
Beat HF	Chronic CHF	Baroreflex activation therapy device for HF related symptoms
Dal-Gene	AA Gene - hyperlipidemia	Evaluate Dalcetrapib in AA genotype patients to reduce Major CV Events
Esperion	Statin Intolerant	Bempedoic Acid vs. Placebo with statin intolerant patients
Invested	High Risk CV - Flu Vaccine	Standard dose vaccine vs high dose vaccine for high risk CV patients to reduce future CV events
Onyx PAS	Resolute ONYX Stent	Post approval registry to assess the continued safety and efficacy of the Resolute Onyx™ stent
Optimize	Invest. Coronary Stent	Inv.Svelte DES-IDS or DES-RX Sirolmus Eluting Stent Systems Vs. Xience or Promus
Optimize IVUS	Invest. Coronary Stent	Inv. Svelte DES-IDS or DES-RX Sirolmus Eluting Stent Systems Vs. Xience or Promus. IVUS @ base and 1 yr
Pioneer III	Invest. Coronary Stent	Inv. BuMA Supreme Biodegradable Drug Coated Coronary Stent vs commercially available DES.
Paradise	New CHF	Acute MI w/ LV systolic dysfunction (LVEF ≤40%); Entresto vs Ramipril to reduce future CV events
Prominent	High TG	Pemafibrate BID vs. Placebo with Diabetic patients who have TG ≥200 and <500 with CAD or PAD
PSR	Medtronic Device implant	Post Market Registry - Pacing/Defib/Left-Heart Leads. Medical Record Review Only
Transcend	Invest. DCB	Surveil DCB- Paclitaxel Drug Eluting Peripheral Balloon vs Medtronic IN.PACT DCB - SFA stenosis
Victoria	Chronic CHF	Chronic CHF with EF <45%; MK-1242 (Vericiguat) vs. placebo, on a background of standard of care.
Victoria Registry	Chronic CHF	Characterizing patients hospitalized for HF decompensation during prescreening for VICTORIA Study
Xience 90	90 day DAPT	90 day DAPT for patients at high risk for bleeding after a PCI with Xience Stent.

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Dal-Gene **DalCor Pharma UK Ltd**

- Use of dalcetrapib to reduce cardiovascular events in subjects with a documented recent ACS and the AA genotype
- Dalcetrapib is a CETP inhibitor with potential to increase HDL
- Inclusion: acute MI, AA genotype

PARADISE **Novartis**

- Entresto vs. Ramipril to reduce HF or CV events
- Entresto was approved for chronic CHF in 2015
- Inclusion: acute HF, EF < 40 must enroll within 7 days of event

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Optimize RCS — Svelte

- Svelte DES-IDS or DES-RX Sirolmus Eluting Stent Systems Vs. Xience or Promus
- Direct Stenting Approach
- Stent system already approved in Europe

AEGIS II — CSL Behring, LLC

- Post ACS infusion CSL 112 or placebo x 4 to reduce future CV events.
- Inclusion: acute MI Must enroll within 5 days of event
- CSL 112 is a novel IV formulation of apoA-1

Thank You!

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INTERVENTIONAL CARDIOVASCULAR TRIALS

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Enrolling Clinical Trials at BayCare

INTERVENTIONAL

ECLIPSE: ***Evaluation of Treatment Strategies for Severe CaLcIfic Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty Technique Prior to Implantation of Drug-Eluting StEnts (ECLIPSE)***

Reveal: ***To evaluate the safety and effectiveness of the Revolution™ Peripheral Atherectomy System in the treatment of infrainguinal lower extremity peripheral arterial occlusive disease***

STOP AF: ***The purpose of the study is to provide data demonstrating the safety and effectiveness of the Arctic Front Advance™ Cardiac CryoAblation Catheter for the treatment of recurrent symptomatic paroxysmal AF, without the requirement that the subjects be drug refractory.***

XIENCE 90: ***A prospective, single arm, multi –center, open label, non-randomized trial to evaluate the safety of 3 month DAPT in HBR (high bleeding risk) subjects undergoing PCI with Xience.***

ArticLine Feasibility Study : ***Phase I trial to collect preliminary safety and effectiveness data on the ArticLine Catheter***

STRUCTURAL HEART AND VALVE CENTER

Joshua Rovin, MD
Medical Director,
Center for Advanced Valve and Structural Heart Care
at Morton Plant Hospital

STRUCTURAL HEART TRIALS at BayCare

Evolut R: ***To demonstrate that the safety and effectiveness of the Medtronic TAVR system as measured by rates of all-cause mortality or disabling stroke at two years is noninferior to SAVR in the treatment of severe aortic stenosis in subjects who have a low predicted risk of operative mortality for SAVR*** **(Low Risk)**

There is now a Continued Access Study as well as use of Evolut R for Bicuspid valves

Portico: ***Further assess the performance and safety profile of the commercially available Portico Valve implanted, using the Delivery System and the Loading System, in patients with severe symptomatic aortic stenosis*** **(High Risk)**

Reflect: ***A Randomized Evaluation of the TriGuard HDH Cerebral Embolic Protection Device and the TriGuard 3 Cerebral Embolic Protection Device to Reduce the Impact of Cerebral Embolic Lesions after Transcatheter Aortic valve Implantation***

APOLLO: ***Transcatheter Mitral Valve Replacement with the Medtronic Intrepid TMVR System in patients with severe symptomatic mitral regurgitation***