DCRI
RECRUITING CV STUDIES

Duke Clinical Research Institute

The Duke Clinical Research Institute, together with its esteemed site community partners, is addressing clinical research challenges that will shape the future of medical care for years to come. Our investigators and study coordinators are true collaborators in fulfilling our mission: *to develop and share knowledge that improves the care of patients around the world through innovative clinical research.*

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ACCELERATION

ACCELERATION

Adenosine Contrast Correlations in Evaluating Revascularization

Currently Recruiting

Participants

What Is ACCELERATION?

This is an investigator-initiated, multicenter, prospective, single-arm trial evaluating the method of delivery of contrast for fractional flow reserve (FFR) with use of the NAVVUS RXi microcatheter FFR system and the CVi automated contrast injector in patients over the age of 18 with intermediate lesion coronary artery disease undergoing non-emergent cardiac catheterization. FFR measurement will be performed with contrast (cFFR) and adenosine (aFFR). Contrast for cFFR is injected via the ACIST CVi contrast injector with standardized settings, and adenosine for aFFR is delivered systemically via intravenous infusion. If percutaneous coronary intervention (PCI) is performed, a final post-PCI contrast, and aFFR is obtained.

ClinicalTrials.gov ID: NCT03557385

Patient Population

Patients over the age of 18 years. All participants who are clinically stable and undergoing non-emergent cardiac catheterization for appropriate indications. A diagnostic angiogram reveals at least one moderate (40-70%) stenosis by angiographic assessment.

Study Objectives

- Determine the accuracy and correlation of contrast FFR (cFFR) using the ACIST CVi automated contrast injector to the current gold-standard adenosine FFR (aFFR).
- Evaluate the association of post-percutaneous coronary intervention (PCI) FFR to long-term clinical outcomes (death, myocardial infarction [MI], target vessel revascularization [TVR]) with up to one-year follow-up.

Duration of Study Participation

One year

Study Centers

Durham VA, NC

Long Beach VA, CA

University of Minnesota, MN

Metropolitan Heart and Vascular Institute, MN

Vanderbilt University, TN

Sample Size

200 patients

Follow-up

Patients follow up for a standard-of-care visit approximately 30 days after their procedure and are contacted at one year to collect data long-term clinical outcomes (death, myocardial infarction, and target vessel revascularization).

Study Timeline

Recruitment began in January 2019, and the study will conclude in July 2020.

Sponsor/Funding Support

ACIST Medical

Learn More

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AEGIS-II

AEGIS-II

A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Participants with Acute Coronary Syndrome

Currently Recruiting

Sites and participants

What Is AEGIS-II?

AEGIS-II is a phase 3 acute coronary syndrome study that will evaluate the efficacy and safety of CSL112 in reducing the risk of major adverse cardiovascular events (MACE), defined as heart attack, stroke, or cardiovascular death, in patients with acute coronary syndrome (ACS). This includes patients with either ST-elevation myocardial infarction (STEMI) or non-ST-elevation myocardial infarction (NSTEMI), and who are receiving evidence-based medical therapy.

ClinicalTrials.gov ID: NCT03473223

Study Drug

CSL112, Apolipoprotein A-I (Human), is a novel formulation of plasma-derived apoA-I, the primary functional component of HDL.

Duration of Study Participation

Patients will be followed for occurrence of MACE for 365 days from randomization.

Study Centers

Approximately 1,000 sites in ~44 countries, with ~235 of those sites in the U.S.. The study is being managed in collaboration with global academic groups and a global CRO. The DCRI is responsible for site management and monitoring in the U.S..

Sample Size

Approximately 17,000 patients worldwide

Sponsor/Funding Support

CSL Behring

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CAMEO

CAMEO

Cangrelor in Acute Myocardial Infarction: Effectiveness and Outcomes Registry

Currently Recruiting

Sites and participants for retrospective data collection

What Is CAMEO?

CAMEO is a retrospective, observational study to address how, when, and in what patients cangrelor is currently being utilized in clinical practice among sites that have cangrelor on formulary. Additionally, the CAMEO registry will examine how cangrelor is being used to bridge antiplatelet therapy prior to CABG during the NSTEMI admission and in subgroups of STEMI patients where there is concern for adequate oral P2Y12 inhibitor absorption. While pharmacologic data are in evidence for transition between P2Y12 inhibitor medications, this registry will describe timing and dosing of switches between cangrelor and an oral P2Y12 inhibitor.

ClinicalTrials.gov ID: NCT04076813

Study Drug

Cangrelor

Patient Population

Adults who have undergone coronary angiography for a STEMI or NSTEMI

Primary Outcome Measures

1. Number of antiplatelet medications used during hospitalization
   - Time Frame: The time frame is hospitalization through discharge, approximately 3 days.
   - Antiplatelet use, including switching and discontinuation, will be measured by medical record report. The medical record report will include medication start and stop dates and times.
2. Number of bleeding events during hospitalization as measured by medical record report
   - Time Frame: The time frame is hospitalization through discharge, approximately 3 days.

Study Country

U.S.

Sample Size

3,000 participants

Study Timeline

The study began in September 2019 and will continue through October 2022.

Sponsor/Funding Support

Chiesi USA Inc.

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CONNECT-HF

CONNECT-HF

Care Optimization through Patient and Hospital Engagement Clinical Trial for Heart Failure

Currently Recruiting

Participants

What Is CONNECT-HF?

A large-scale, pragmatic, cluster-randomized trial to evaluate a heart failure quality improvement initiative deployed at a health system level, compared with usual care on heart failure (HF) outcomes and HF quality-of-care metrics at 1 year after discharge for patients hospitalized with acute HF and reduced ejection fraction.

ClinicalTrials.gov ID: NCT03035474

Site and Patient Population

Hospitals selected to participate will have the capacity to be randomized to a system-based quality-improvement intervention.

The patient population will consist of male and female patients, ≥18 years of age, with a reduced ejection fraction (left ventricular ejection fraction ≤40%) and admitted to the hospital with a primary reason of acute HF.

Study Objectives

Primary: Assess the effect of a customized, multifaceted QI initiative, compared with usual care, on HF outcomes and HF quality metrics at one year after discharge for participants with acute HF and reduced ejection fraction.

Secondary: To examine the effect of two quality-improvement initiatives compared to usual care on the following endpoints:

- Per-opportunity adherence rate for site-level HF discharge quality measures
- Patient-level health care expenditures at 6 months and 1 year post-discharge
- Patient-reported medication adherence at 6 months and 1 year post-discharge
- Change in KCCQ and EQ-5D from discharge to 6 weeks and 6 months post-discharge

Duration of Study Participation

~12 months

Sample Size

7,040 participants

Follow-up

Follow-up will be conducted via the DCRI call center at 6 weeks and 3, 6, and 12 months post-discharge.

Sponsor/Funding Support

Novartis

Learn More

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COORDINATE-Diabetes

COORDINATE-Diabetes

Coordinating Cardiology Clinics Randomized Trial of Interventions to Improve Outcomes

Currently Recruiting

Sites and participants. Sites must be cardiology practices with a minimum of three physicians or APPs with independent patient populations. Patients are enrolled during a routine clinic visit.

What Is COORDINATE-Diabetes?

A cluster-randomized clinical trial to test the effectiveness of an innovative, clinic-level educational intervention to improve the management of patients with T2DM and CVD. Sites will be randomized to a basic education arm or an intensive educational intervention arm, to improve evidence-based care for patients with diabetes and cardiovascular disease. Data collection will continue for all participants for at least 12 months after enrollment. The primary outcome is the proportion of patients achieving guideline-recommended management of diabetes and cardiovascular disease measured as a composite score of three at 12 months. Social Security Number information will be collected to conduct a National Death Index search for vital status at 2- and 5- years.

ClinicalTrials.gov ID: NCT03936660

Unique Aspects of Project

Patients receive standard care for their cardiovascular disease and diabetes. The study is focused on educating site staff regarding guideline-based care.

Intervention

Clinic-level intensive education and mentoring related to guideline-based care.

Patient Population

Adults with ASCVD and diabetes

Study Objectives

To test the effectiveness of implementing a clinic-level multifaceted intervention that includes establishing cardiology and endocrinology partnerships and evidence-based care pathways to improve the medical management and care of patients with T2DM and cardiovascular disease.

Duration of Study Participation

12 months

Study Centers

46 sites in the U.S.

Sample Size

1,380 patients (30 per site)

Follow-up

Sites will collect EHR and patient-reported data regarding medications, procedures, and hospitalizations. DCRI conducts a vital status search at 2- and 5-years using SSN and the National Death Index.

Study Timelines

The first patient was enrolled in July 2019. Enrollment will continue through November 2020.

Substudies

An observational analysis will be conducted in tandem with a subset of sites with existing datamarts containing EHR data in a common data model (CDM) format. The objectives of this observational analysis are to describe the clinical characteristics, management, and outcomes of patients with T2DM and CVD in current practice across an array of health systems in the U.S. and to characterize trends in the quality of care for patients with T2DM and CVD over time.

Sponsor/Funding Support

Boehringer Ingelheim Pharmaceuticals, Inc.
Lilly USA, LLC

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HEART-FID

HEART-FID

Injectafer® as Treatment for Heart Failure with Iron Deficiency (HEART-FID)

Currently Recruiting

Participants

What Is HEART-FID?

A double-blind, multicenter, prospective, randomized, placebo-controlled study to assess the effects of IV ferric carboxymaltose compared to placebo on the 12-month rate of death, hospitalization for worsening heart failure, and the 6-month change in the 6-minute walk test (6MWT) for patients in heart failure with reduced ejection fraction and iron deficiency.

ClinicalTrials.gov ID: NCT03037931

Study Drug

Injectafer® (ferric carboxymaltose)

FCM is approved for the treatment of iron deficient anemia and is an investigational product in this study for patients in heart failure with iron deficiency.

Patient Population

Adults 18 years or older with stable NYHA class II–IV heart failure and reduced left ventricular ejection fraction. Participants must meet all inclusion/exclusion criteria, including the ability to perform a 6MWT at the time of randomization and meet laboratory requirements for hemoglobin and serum ferritin.

Study Objectives

To determine the efficacy and safety of iron therapy using intravenous ferric carboxymaltose relative to placebo in the treatment of participants in heart failure with a reduced ejection fraction and iron deficiency.

Duration of Study Participation

Approximately 4 years for the first patient enrolled

Study Centers/Countries

North America, Australia, and New Zealand

Sample Size

Approximately 3,000 patients

Follow-up

Study drug administration will occur on Day 0 and Day 7 (±2) as an undiluted slow IV push, with additional study visits planned at 3-month intervals and additional dosing administered every 6 months as applicable.

Sponsor/Funding Support

American Regent, Inc.

Learn More

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PISCES III

PISCES III

Phase IIb Investigation of Stem Cells in Stroke

Currently Recruiting

Sites and participants

What is PISCES III?

PISCES III is a clinical research study to determine whether stem cells injected into a damaged area of the brain can improve function in people with ongoing disability following an ischemic stroke (a stroke that occurs when blood flow to the brain is blocked, such as by a clot). The study drug is CTX0E03 DP or Placebo/Sham.

ClinicalTrials.gov Identifier: NCT03629275

Patient Population

Adults between 35 and 75 years of age (inclusive), who have limited movement in their arms and/or legs 6-24 months following an ischemic stroke. This study is open to U.S. participants only.

Study Objective

To determine if a study drug, which is made from stem cells, will improve the functional ability to perform activities of daily living in survivors 6-24 months following an ischemic stroke. Ischemic stroke is the most common type of stroke and occurs when blood flow to the brain is blocked, such as by a clot. This study is open to U.S. participants only.

Duration of Study Participation

12 months of study participation and a subsequent follow up/ observation period

Study Centers

Approximately 40 centers across the U.S.

Sample Size

130 participants

Follow-up

A long-term follow-up study is planned.

Sponsor/Funding Support

ReNeuron, Ltd.

Learn More

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https://pisces3.org

SAFE STEMI

SAFE STEMI

SAFE STEMI for Seniors: Study of Access Site for Enhancing PCI in STEMI for Seniors

Currently Recruiting

Sites

Enrolling participants by invitation only

What Is SAFE STEMI?

The SAFE STEMI for Seniors: Study of Access Site for Enhancing PCI in STEMI is an investigator-initiated, multicenter, randomized, open-label, unblinded, active, and historical controlled trial in which approximately 875 seniors undergoing urgent PCI from at least 70 centers in North America will be enrolled. All consented participants will undergo attempted radial arterial access.

ClinicalTrials.gov ID: NCT02939976

Unique Aspects of Project

MDEpiNet protocol using the CMS database for patient follow-up information.

Treatment/Intervention

Medtronic Resolute® Family of stents (required)

Verrata®, Verrata Plus®, and any subsequent marketed Volcano pressure wire technology (required)

Terumo Glidesheath Slender™ and TR Band® Radial Artery Compression Device (optional)

Patient Population

Men and women 60 years of age and older with chest pain ≤12 hours and ST-elevation myocardial infarction or left bundle branch block (LBBB) on ECG with intent to perform percutaneous coronary intervention (PCI) via right or left radial arterial access.

Study Objectives

To simultaneously address four potential advances in STEMI care for patients at least 60 years old:

- To examine the effectiveness of zotarolimus-eluting stents for radial primary PCI in STEMI.
- To evaluate the safety and benefit of iFR-guided complete revascularization vs. infarct artery-only revascularization in

primary PCI of patients with multi-vessel CAD.

- To obtain data on the real-world application of radial access for primary PCI in the public health focus on an elderly population.
- To evaluate the safety of the Terumo Glidesheath Slender and TR Band on an elderly population.

Duration of Study Participation

12 months

Study Centers

70 sites in the U.S. and Canada

Sample Size

875 participants

Follow-up

Patients will be seen by sites for their standard of care follow-up visit approximately 30 days after their procedure. Patients will be contacted at 1 year by the DCRI Outcomes Call Center to collect data for the primary endpoint analysis. Medicare claims data (parts A and B) will be collected for U.S. participants at 18 months post-procedure after the final patient is enrolled.

Study Timelines

First patient enrolled by August 30, 2017. Enrollment planned to close on March 2022.

Sponsor/Funding Support

Sponsor: Dr. David F. Kong, Duke Clinical Research Institute

Funding support provided by:

Medtronic Vascular, Inc.
Philips Volcano Corporation
Terumo Medical Corporation

Learn More

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SPIRRIT HFpEF

SPIRRIT HFpEF

Spironolactone Initiation Registry Randomized Interventional Trial in Heart Failure With Preserved Ejection Fraction

Currently Recruiting

Participants

What Is SPIRRIT HFpEF?

SPIRRIT HFpEF is a unique pragmatic trial being implemented in both Sweden and the U.S.. The protocol chair is Dr. Lars Lund of the Karolinska Institute in Sweden and co-chair, Dr. Bertram Pitt, University of Michigan. Heart failure with preserved ejection fraction (HFpEF) is common and deadly but without therapy. Inconclusive studies suggest spironolactone may be effective in HFpEF, but it is generic and is not studied by industry. SPIRRIT is a unique registry-randomized clinical trial that will test the hypothesis that spironolactone plus standard of care compared to standard of care alone reduces the composite of cardiovascular (CV) mortality and heart failure (HF) hospitalization.

ClinicalTrials.gov ID: NCT02901184

Study Drug

Spironolactone or eplerenone if spironolactone is not tolerated.

Patient Population

Male and female HFpEF patients in the Swedish Heart Failure Registry (2550 patients) and HFpEF patients in U.S. (650 patients).

Intervention/Treatment

Spironolactone will be prescribed by the Investigator and filled by patient at conventional pharmacies as 25 mg tablets. The treatment will be on top of standard care. Initial dose is 25 mg/day, which will be increased to target dose 50 mg/day if tolerated. Eplerenone can be prescribed if spironolactone is not tolerated. Patients in the control arm will get the standard care alone.

Outcome Measures

Primary Outcome Measures:

- Time to CV death or first HF hospitalization

Secondary Outcome Measures:

- Time to CV death
- Incidence rate for total HF hospitalizations or CV death
- Incidence rate for total HF hospitalizations
- Time to HF hospitalizations
- Time to all-cause mortality
- Incidence rate for all-cause hospitalizations
- Time to all-cause hospitalizations
- Incidence rate for all-cause hospitalizations or all-cause mortality

Duration of Study Participation

The trial is event-driven with an enrollment period of 3 years and a total study duration of 5 years.

Study Countries

Sweden

U.S.

Sample Size

Approximately 3,200 participants will be enrolled.

Follow Up

After the baseline visit, the sites will follow up at 1 week, 4 weeks, 6 months, and 12 months. Starting at 18 months, the DCRI Outcomes Call Center will follow up with study participants every 6 months until the end of the study.

Sponsor/Funding Support

Uppsala Clinical Research Center

U.S. Funding Support

National Heart, Lung, and Blood Institute (NHLBI)
Trial Innovation Network

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TACT2

TACT2

Trial to Assess Chelation Therapy (TACT) 2

Currently Recruiting

Participants

What Is TACT2?

TACT2 will build on the positive results of TACT1, an NIH-sponsored multicenter, double-blind efficacy and safety trial for edetate disodium (EDTA) chelation therapy in individuals with coronary artery disease, the leading cause of death for both men and women in the U.S. Plans for TACT2 include targeting the population of patients who received the greatest benefits from EDTA treatment (those with a prior heart attack and diabetes) and determining if the positive results from TACT1 can be replicated in diabetic patients who have experienced a myocardial infarction, a particularly high-risk group of patients in need of effective therapy.

ClinicalTrials.gov ID: NCT02733185

Study Drug

Patients will be randomly allocated (1:1:1:1) to four factorial groups:

1. Active chelation + active OMVM (oral multivitamins and multiminerals)
2. Active chelation + placebo OMVM
3. Placebo chelation + active OMVM
4. Placebo chelation + placebo OMVM

Patient Population

Diabetic patients age 50 or older with a prior myocardial infarction (MI) and serum creatinine ≤2.0 mg/dL.

Study Objectives

TACT2 will replicate the findings of TACT1, which found a striking reduction of recurrent cardiovascular events in post-MI diabetic patients receiving edetate disodium-based chelation therapy.

The primary objective of TACT2 is to determine if the chelation-based strategy increases the time to the first occurrence of any of the components of the TACT2 primary endpoint—all-cause mortality, myocardial infarction, stroke, coronary

revascularization, or hospitalization for unstable angina—compared to the placebo chelation strategy.

The secondary objectives of TACT2 are to determine if the chelation-based strategy:

- Reduces the overall rate of occurrence of the events that define the primary TACT2 endpoint (as stated above).
- Increases the time to the first occurrence of a composite endpoint—cardiovascular mortality, recurrent myocardial infarction, or stroke—compared to placebo chelation strategy.
- Increases the time to all-cause mortality compared to placebo chelation strategy.

Duration of Study Participation

Up to 5 years. Enrollment opened October 3, 2016.

Study Centers

100 sites in North America and Canada

Sample Size

1,200 patients enrolled over 3 years

Study Timelines

5 years total

Learn More

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TARGET-HFDM

TARGET-HFDM

Technology to improve drug Adherence and Reinforce Guideline-based Exercise Targets in patients with Heart Failure and Diabetes Mellitus

Currently Recruiting

Participants

What Is TARGET-HFDM?

TARGET-HFDM is a multicenter, randomized, controlled clinical trial in eligible participants with heart failure and diabetes mellitus. The study will utilize a wearable activity monitor and a medication adherence training tool. Activity levels (step counts), self-reported quality of life, medication adherence, and relevant clinical measures will be collected from all study participants. Those participants randomized to mHealth intervention will also receive personalized, directed feedback via text messaging about individualized activity goals and medication adherence training using the Pillbox tool. There are five study assessments, including clinical visits (enrollment, 1 month, 3 months, and 6 months) and a phone call at Day 7.

ClinicalTrials.gov ID: NCT02918175

Patient Population

Ambulatory adults with chronic heart failure (regardless of ejection fraction) and diabetes mellitus meeting eligibility criteria for enrollment. Participants must have access to a compatible smartphone (either iOS or Android).

Study Objective

The overall objective of this study is to test a personalized mHealth intervention designed to increase physical activity and improve medication adherence in a randomized controlled trial of an at-risk population with concomitant heart failure and diabetes mellitus. The underlying hypothesis is that the proposed mHealth intervention can favorably impact specific health behaviors (physical activity and medication adherence) and physiologic measures of disease status (NT-proBNP and HbA1c) for both heart failure and diabetes. Additional hypotheses to be tested will assess the persistence of behavioral changes (daily physical activity and medication adherence) and physiologic measures (NT-proBNP, HbA1c) beyond the 3-month time point of the active mHealth intervention (i.e., through 6 months).

Duration of Study Participation

6 months

Study Centers

New York-Presbyterian Brooklyn Methodist Hospital (NY)

Inova (VA)

Duke University (NC)

Stanford University (CA)

Massachusetts General Hospital (MA)

Sample Size

200 participants

Study Timelines

Enrollment began in August 2017. Participant recruitment will last approximately 24 months.

Sponsor/Funding Support

American Heart Association—Strategically Focused Research Network for Heart Failure

Learn More

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TRANSFORM-HF

TRANSFORM-HF

ToRsemide compArisoN with furoSemide FOR Management of Heart Failure

Currently Recruiting

Sites and participants

What Is TRANSFORM-HF?

A randomized, unblinded, two-arm, multicenter clinical trial of patients with heart failure who are hospitalized. Patients will be randomized 1:1 to either oral torsemide or oral furosemide prior to hospital discharge. Dosing will be at discretion of local provider, with dose equivalency guidance provided.

Trial enrollment occurs before hospital discharge, at the discretion of the health care provider. As appropriate, adherence to the randomized medication will be encouraged during the remainder of hospitalization and will continue post-discharge. Patients will receive follow-up per standard care without any additional study-specific visits.

Patients will have follow-up phone calls administered by the DCRI Call Center starting at 30 days, 6 months, and 12 months for assessments of vital status, interval hospitalizations, adherence, and quality of life. Some patients, depending on when they are randomized, may have one, two, or three more follow-up calls administered by the DCRI Call Center, but no patient should have more than about six calls in total (and calls will be approximately six months apart). “Central follow-up” and collection of hospital discharge summaries will occur via IRB-approved mechanisms.

ClinicalTrials.gov ID: NCT03296813

Unique Aspects of Project

Pragmatic study design

Study Drugs

Furosemide and torsemide

Patient Population

The population will exclusively enroll patients while they are hospitalized. Eligible patients will have an active history of chronic heart failure prior to hospitalization or a new diagnosis of heart failure during the index hospitalization.

Duration of Study Participation

At least 12 months, but no more than 30 months total

Study Centers/Countries

50 study sites, U.S. only

Sample Size

6,000 patients

Follow-up

All patients receive follow-up phone call at 30 days, 6 months, and 12 months; some patients, depending on timing of their randomization, may receive additional calls at months 18, 24, and 30.

Sponsor/Funding Support

National Heart, Lung, and Blood Institute (NHLBI)

Learn More

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NOTES

NOTES

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