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, share, and implement knowledge that improves health around the world through innovative clinical research.
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) using 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 Health Care System, NC
VA Long Beach Healthcare System, 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 2021.

Sponsor/Funding Support
ACIST Medical

Learn More
Marjan Cobbaert, MPH, Project Leader
marjan.cobbaert@duke.edu
919-668-9740
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

Learn More
Lynn Perkins, Project Leader
lynn.perkins@duke.edu
919-668-8634
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.

Learn More
Linda Davidson-Ray, Assistant Director of Operations, Outcomes
linda.davidson.ray@duke.edu
919-668-8724
COORDINATE-Diabetes

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 will conduct 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, and as of April 2021, 865 participants are enrolled.

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

Learn More
Laura Webb, Project Leader
laura.webb@duke.edu
919-668-8977
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 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
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Medtronic Vascular, Inc.
Philips Volcano Corporation
Terumo Medical Corporation

Learn More
Britt Barham, Project Leader
britt.barham@duke.edu
919-619-2550
SPIRRIT HFpEF

Spironolactone Initiation Registry Randomized Intervventional 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 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 (2,550 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 and the 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 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

Learn More

Sweden: SPIRRIT@ucr.uu.se
U.S.: dcri-SPIRRIT@dm.duke.edu

Lisa Hatch, BS, MPH, Project Leader
lisa.hatch@duke.edu
919-748-9701
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 6 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
Robert Mentz, MD
robert.mentz@duke.edu

Shelby Morgan, Project Lead
shelby.morgan@duke.edu