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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ARAMIS

Currently Recruiting
Patients only

What Is ARAMIS?
The ARAMIS Registry is a multicenter, prospective, observational study of acute ischemic stroke (AIS) and intracerebral hemorrhage (ICH) patients on home anticoagulation therapy, based on the existing GWTG-Stroke infrastructure. ARAMIS is enrolling consecutive patients (AIS on new oral anticoagulants [NOA] and ICH on either NOA or warfarin) from 90–100 GWTG-Stroke hospitals over 5 years.

In addition to the standard GWTG-Stroke data collection, key data points will be abstracted (retrospectively) from the medical records regarding medications prior to admission, coagulation tests, brain imaging, stroke severity, functional status, inpatient treatment (tPA for AIS and anticoagulant reversal agents for ICH), discharge medications, and outcomes.

ClinicalTrials.gov Identifier: NCT02478177

Patient Population
Patients hospitalized with either AIS or ICH, patients on anticoagulant therapies.

Study Objectives
- Examine the prevalence of prior NOA use in AIS and ICH patients.
- Describe diagnostic tests being used to assess level of anticoagulation when a patient comes in with AIS or ICH on one of the novel agents.
- Characterize use of thrombolytic therapy in AIS patients on NOA as compared with those on warfarin.
- Document current practice patterns for stroke patients on NOA and determine how treatment and clinical outcomes vary by NOA and warfarin therapy.
Duration of Study Participation

Approximately 1 year

Follow-up

Follow-up will be conducted at 3 and 6 months via a centralized call center in patients who provide informed consent to participate in the follow-up study.

Sponsors

Janssen, Genentech, and Daiichi Sankyo

Learn More

Khaula Baloch, Project Leader
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A Study of Apixaban versus Vitamin K Antagonist for the Prevention of Stroke or Systemic Embolism and Bleeding in Patients with Nonvalvular Atrial Fibrillation and Acute Coronary Syndrome/Percutaneous Coronary Intervention

Currently Recruiting

Subjects

What Is AUGUSTUS?
The optimal treatment for nonvalvular atrial fibrillation (NVAF) patients requiring anticoagulation but who also have an indication for prolonged dual antiplatelet therapy (for either ACS or PCI) is uncertain. The AUGUSTUS study is an open-label, 2x2 factorial, randomized, controlled clinical trial to evaluate the safety of apixaban versus vitamin K antagonist and aspirin versus aspirin placebo in patients with atrial fibrillation and acute coronary syndrome (ACS) or percutaneous coronary intervention (PCI). It is designed to help determine the optimal antithrombotic strategy in patients with atrial fibrillation and ACS or PCI.

At the time of enrollment, each patient who meets eligibility criteria will be randomized using a 2x2 factorial design to either open-label apixaban or vitamin K antagonist and to either blinded low-dose aspirin or aspirin placebo, with choice of P2Y12 inhibitor at the discretion of the investigator. Study drugs will be administered for a 6-month treatment period.

The primary endpoint will be ISTH major or non-major clinically relevant bleeding during the follow-up period.

ClinicalTrials.gov ID: NCT02415400

Patient Population
Patients with a history of NVAF requiring anticoagulation presenting with recent ACS or PCI and planned treatment with P2Y12 inhibitor and oral anticoagulation for at least 6 months will be evaluated for eligibility within 14 days of their index ACS or PCI event.

Patients with or without prior oral anticoagulant treatment are eligible for this trial.
Study Centers
~600

Countries
~35 countries in North America, Latin America, Europe, and Asia-Pacific
Currently, 2,657 patients have been randomized across 29 countries.

Sample Size
4,600

Follow-up
6 months

Sponsors
Bristol-Myers Squibb Research and Development
Pfizer, Inc.

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CONNECT-HF

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

Currently Recruiting

Sites and subjects

What Is CONNECT-HF?

A large-scale, pragmatic, cluster-randomized clinical trial to evaluate the effect of two quality-improvement initiatives compared to 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: To assess the effect of two quality-improvement initiatives compared to usual care on HF outcomes (i.e., composite of HF readmissions or all-cause mortality) and HF quality metrics (i.e., as assessed by an opportunity-based composite score) at 1 year after discharge for patients 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 healthcare 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
8,000

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

Sponsors
Novartis

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Harvoni Cardio Pulmonary

Harvoni® (Sofosbuvir Ledipasvir Fixed Dose Combination) in Subjects Infected with Chronic Hepatitis C and Advanced Heart Failure or Lung Disease

Currently Recruiting

Subjects

What Is Harvoni Cardio Pulmonary?

An open-label, phase IV multicenter study to evaluate the safety and tolerability of sofosbuvir (SOF) + ledipasvir (LDV) fixed dose combination (FDC) for 12–24 weeks in subjects with chronic HCV and advanced heart failure or lung disease. This is a study in HCV-infected adult patients who also have either advanced cardiac disease or advanced lung disease. Advanced cardiac disease is defined as a marked limitation of physical activity, or discomfort upon physical activity. The patients in the advanced cardiac disease group must also have been hospitalized for heart failure within the last 12 months.

Advanced lung disease is defined as patients who have been diagnosed with chronic obstructive pulmonary disease (COPD) or interstitial lung disease (ILD). Patients in the COPD group must have abnormalities in their forced expiratory volume (FEV) test, which measures the amount of air exhaled. They may or may not need supplemental oxygen. Patients in the ILD group must have been diagnosed with ILD and require supplement oxygen at all times.

ClinicalTrials.gov Identifier: NCT02858180

Study Drug

Sofosbuvir ledipasvir

Patient Population

Adults with chronic HCV and advanced heart failure or lung disease
Study Objectives

Primary: To evaluate the safety and tolerability of sofosbuvir (SOF) + ledipasvir (LDV) fixed dose combination (FDC) for 12–24 weeks in subjects with chronic HCV and advanced heart failure or lung disease.

Secondary: To determine the antiviral efficacy of SOF/LDV FDC for 12–24 weeks in subjects with chronic HCV and advanced heart failure or lung disease as measured by sustained virologic response 12 weeks after discontinuation of therapy (SVR12 defined as HCV RNA < lower limit of quantitation 12 weeks post-treatment).

Duration of Study Participation

12–24 weeks of treatment followed by 12 weeks of follow-up

Study Countries

U.S. only

Sample Size

Up to 50 participants will be enrolled.

Study Timelines

Currently enrolling

Sponsor/Funding Support

Dr. Andrew Muir
Gilead Sciences

Learn More

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HEART-FID

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

Currently Recruiting
Patient enrollment began in March 2017.

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 Identifier: 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
Luitpold Pharmaceuticals

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ISCHEMIA
International Study of Comparative Health Effectiveness with Medical and Invasive Approaches

Currently Recruiting
Subjects

What Is ISCHEMIA?
An international, multicenter, randomized controlled trial to determine the best treatment strategy for stable higher-risk patients with at least moderate ischemia on stress testing. Patients will be assigned at random to a routine invasive strategy with cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) or to a conservative strategy of OMT, with catheterization and revascularization reserved for those who fail OMT.

ClinicalTrials.gov Identifier: NCT01471522

Sponsor
National Heart, Lung, and Blood Institute

Trial Leadership
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David Maron (Stanford University)
Sean O’Brien (Duke University)
Karen Alexander (Duke University)
Dave Williams (Brigham & Women’s Hospital)
Bruce Ferguson (East Carolina Heart Institute)
Robert Harrington (Stanford University)
William Boden (Albany Medical Center VA)
Gregg Stone (Columbia University)
Yves Rosenberg (NHLBI)

Coordinating Center Collaborators
New York University School of Medicine
Vanderbilt University
Duke Clinical Research Institute
Emory University
Mid America Heart Institute
Patient Population
Patients with moderate or severe ischemia detected by clinically indicated stress test.

Study Centers
375 sites in 35 countries

Follow-up
Minimum of 1 year and up to 4 years, with a primary endpoint of time to cardiovascular death or first occurrence of non-fatal myocardial infarction.

Study Timelines
Enrollment initiated in the third quarter of 2012, with enrollment completion anticipated at the end of 2017.

Ancillary Studies
**ISCHEMIA-CKD** (PI: Sripal Bangalore, New York University): Participants with advanced chronic kidney disease (eGFR <30 or on dialysis) and moderate or severe ischemia will be assigned at random to an initial invasive or conservative strategy.

**CIAO-ISCHEMIA** (PI: Harmony Reynolds, New York University): Investigation of the correlation between changes in symptoms and changes in ischemia over 1 year in patients with moderate or severe ischemia who are enrolled in ISCHEMIA but are not randomized due to the absence of obstructive CAD on coronary CT angiography.

Study Website
[ischemiatrial.org](http://ischemiatrial.org)

Learn More about Participating
Investigator and Coordinator Meeting
Monday, November 13, 2017
7:15 p.m.—8:20 p.m.
The Gathering Room
Hyatt House at Anaheim Resort/Convention Center
1800 S. Harbor Blvd.
Anaheim, CA 92802

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ISCHEMIA-CKD

International Study of Comparative Health Effectiveness with Medical and Invasive Approaches—Chronic Kidney Disease (ancillary trial)

What Is ISCHEMIA-CKD?

An international, multicenter, randomized, controlled ancillary trial, running seamlessly with the ISCHEMIA trial, to determine the best treatment strategy for higher-risk patients with stable ischemic heart disease (SIHD) and advanced chronic kidney disease (CKD).

Patients will be assigned at random to a routine invasive strategy with cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) or to a conservative strategy of OMT, with catheterization and revascularization reserved for those who fail OMT.

This is the largest treatment strategy trial in patients with advanced CKD and SIHD.

ClinicalTrials.gov Identifier: NCT01985360

Sponsor

National Heart, Lung, and Blood Institute

Coordinating Center Collaborators

New York University School of Medicine
Duke Clinical Research Institute
Trial Leadership
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Judith Hochman (New York University)
Sean O’Brien (Duke University)
Bruce Ferguson (East Carolina Heart Institute)
William Boden (Albany Medical Center VA)
Glenn Chertow (Stanford University)
David Maron (Stanford University)
Dave Williams (Brigham & Women’s Hospital)
Robert Harrington (Stanford University)
Gregg Stone (Columbia University)

Patient Population
Patients with moderate or severe ischemia detected by clinically indicated stress test and with advanced CKD (defined as those with estimated glomerular filtration rate [eGFR] <30 or on dialysis).

Study Centers
~320 sites in 33 countries

Follow-up
Minimum of 1.5 years and up to 4 years, with a primary endpoint of time to death or first occurrence of nonfatal myocardial infarction.

Study Timelines
Enrollment initiated in the first quarter of 2014, with enrollment completion anticipated at the end of 2017.

Study Website
ischemiackd.org

Learn More about Participating
Investigator and Coordinator Meeting
Monday, November 13, 2017
7:15 p.m.–8:20 p.m.
The Gathering Room
Hyatt House at Anaheim Resort/Convention Center
1800 S. Harbor Blvd.
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PIioneer-HF

Comparison of Sacubitril/Valsartan versus Enalapril on Effect on NT-proBNP in Patients Stabilized from an Acute Heart Failure Episode

Currently Recruiting Subjects

What Is PIONEER-HF?

A multicenter, randomized, double-blind, double-dummy, parallel group, active-controlled 8-week study to evaluate the effect of sacubitril and valsartan (LCZ696) versus enalapril on changes in NT-proBNP and safety and tolerability of in-hospital initiation of LCZ696 compared to enalapril in HFrEF patients who have been stabilized following hospitalization for acute decompensated heart failure (ADHF).

ClinicalTrials.gov Identifier: NCT02554890

Patient Population

The study population will consist of 882 male and female subjects, ≥18 years of age, admitted to hospital for acute decompensated heart failure.

Study Objectives

The primary objective of this study is to assess the effect of in-hospital initiation of sacubitril and valsartan tablets vs. enalapril on the time-averaged proportional change of NT-proBNP from baseline in patients who have been stabilized following hospitalization for acute decompensated heart failure and reduced ejection fraction (left ventricular ejection fraction [LVEF] ≤40%). Weeks 4 and 8 will be included in the analysis (primary analysis time point).

Secondary objectives are to examine the effect of sacubitril and valsartan tablets vs. enalapril on change in:

- Incidence of symptomatic hypotension during 8 weeks of treatment
- Incidence of hyperkalemia (potassium >5.5 mEq/L) during 8 weeks of treatment
- Incidence of angioedema during 8 weeks of treatment
- Biomarkers: high-sensitivity troponin (hs-troponin), urinary cGMP at 4 and 8 weeks, and BNP:NT-proBNP ratio
Study Drug
Sacubitril and valsartan vs. enalapril

Duration of Study Participation
12 weeks, including 4 weeks of open-label Entresto®

Study Centers
Approximately 150 centers in the U.S.

Sponsor
Novartis

Learn More
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**PRIME-HF**

**Predischarge Initiation of Ivabradine in the Management of Heart Failure**

Currently Recruiting

Sites and subjects

**What Is PRIME-HF?**

PRIME-HF is a multicenter, randomized, open-label study comparing pre-discharge initiation of ivabradine to usual care following a hospitalization for acute heart failure.

ClinicalTrials.gov Identifier: NCT02827500

**Population**

Hospitalized patients with acute heart failure and the following criteria: LVEF ≤35%, NYHA class II–IV symptoms despite guideline-directed medical therapy, documented clinical stability, and sinus rhythm with a resting heart rate of ≥70 bpm.

**Intervention**

Pre-discharge initiation of twice-daily oral ivabradine (starting at 5 mg BID with encouraged dose titration to 7.5 mg BID) versus usual care.

**Study Objectives**

To test the primary hypothesis that, compared with usual care, a treatment strategy of initiation of ivabradine prior to discharge for a hospitalization for acute HF will be associated with a greater proportion of participants using ivabradine at 180 days.

To assess the impact of pre-discharge initiation of ivabradine on:
- Heart rate and change in heart rate from baseline to 180 days
- Median heart rate at 180 days
- Kansas City cardiomyopathy questionnaire
- Patient global assessment rating scale
Study Centers
50 clinical centers in the U.S.

Sample Size
450 subjects

Duration of Study Participation
180 days of post-discharge follow-up

Study Timelines
Subject enrollment began in September 2016.

Sponsors
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Amgen

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RENAL-AF

Renal Hemodialysis Patients Allocated Apixaban versus Warfarin in Atrial Fibrillation (RENAL-AF)

Currently Recruiting

Sites and subjects

What Is RENAL-AF?

A prospective, randomized, open-label, blinded endpoint evaluation trial.

ClinicalTrials.gov Identifier: NCT02942407

Study Drug

Apixaban (5 mg BID or 2.5 mg BID)

Treatment/Intervention

Patients will be randomized to apixaban versus warfarin and be treated for up to 15 months.

Patient Population

The patient population consists of patients with end-stage renal disease (ESRD) on hemodialysis who have atrial fibrillation (AF) and stroke risk factors and who are candidates for oral anticoagulation.

Study Objectives

The primary objective is to compare the safety of apixaban versus warfarin with respect to major or clinically relevant non-major bleeding in patients with atrial fibrillation and end-stage renal disease (ESRD) on hemodialysis.

Secondary and other objectives include:

- Evaluation of stroke and systemic embolism event rates with warfarin and apixaban in patients with AF and ESRD on hemodialysis
- Evaluation of mortality rates with warfarin and apixaban in patients with AF and ESRD on hemodialysis
- Evaluation of persistence (meaning the duration of time from initiation to discontinuation of therapy) of and adherence (meaning the extent to which a patient acts in accordance
with the prescribed interval and dose of a dosing regimen) to warfarin and apixaban in patients with AF and ESRD on hemodialysis

- Evaluation of the pharmacokinetics and pharmacodynamics of apixaban in patients with AF and ESRD on hemodialysis
- Analysis of outcomes and treatment effect according to levels of cardiovascular biomarkers at baseline

Duration of Study Participation
Up to 15 months

Follow-up
Maximum follow-up of 15 months, and the target follow-up will be a mean of 12 months

Study Centers
Approximately 80–100 sites in the U.S.

Sample Size
Approximately 762 patients

Study Timelines
First subject randomized January 2017
Estimate for enrollment: 18 months

Principal Investigators
Glenn Chertow, MD, MPH (Stanford University)
Christopher Granger, MD

Sponsor/Funding Support
Christopher Granger, MD
Bristol-Myers Squibb (investigator initiated)

Study Website
renal-af.org

Learn More
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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 subjects 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 65 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 65 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 subjects

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. subjects 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 November 30, 2019.

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

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TACT2

Trial to Assess Chelation Therapy (TACT) 2

Currently Recruiting

Sites and subjects

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 Identifier: 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

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

Currently Recruiting

Subjects

What Is TARGET-HFDM?

TARGET-HFDM is a multicenter, randomized, controlled clinical trial in eligible subjects 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 subjects. Those subjects 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. Subjects 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
Currently enrolling at NY Methodist Presbyterian Hospital (NY), Inova (VA), and Duke (NC). Soon to be enrolling at Stanford (CA) and MassGen (MA).

Sample Size
200

Study Timelines
Enrollment began in August 2017. Subject accrual will last approximately 24 months.

Sponsor/Funding Support
American Heart Association—Strategically Focused Research Network for Heart Failure

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TRANSFORM-HF

ToRsemide compArisoN with furoSemide FOR Management of Heart Failure

Currently Recruiting Sites

What Is TRANSFORM-HF?
A randomized, unblinded, two-arm, multicenter clinical trial of patients with heart failure who are hospitalized. (Heart failure need not be the reason for hospitalization.) Patients will be randomized 1:1 to either oral torsemide or oral furosemide prior to hospital discharge. Oral dosing of torsemide compared to furosemide will be 1 mg:2 mg. The specific loop diuretic dose will be at the discretion of the treating physician with the above-noted conversion.

Trial enrollment occurs before hospital discharge, at the discretion of the healthcare 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 30-day, 6-month and 12-month follow-up phone contacts for assessments of vital status, interval hospitalizations, adherence, and quality of life. “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
Approximately 12 months

Study Centers/Countries
50 study sites, U.S. only

Sample Size
6,000 patients randomized

Follow-up
Follow-up phone call at 30 days, 6 months, and 12 months

Funding Support
National Heart, Lung, and Blood Institute (NHLBI)

Learn More
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VIVID

Educational Videos to Address Racial Disparities in Implantable Cardioverter Defibrillator Therapy Via Innovative Designs

Currently Recruiting Patients

What Is VIVID?

VIVID is an investigator-initiated study, funded by Patient-Centered Outcomes Research Institute. It is a multicenter clinical randomized trial for African-American individuals with heart failure, at risk for sudden cardiac death (SCD), and eligible for an implantable cardioverter defibrillator (ICD).

ClinicalTrials.gov Identifier: NCT02819973

Intervention

Participants enrolled in the study will be randomized using the VIVID application on an iPad to one of three arms: A) video with African-American participants, B) video with Caucasian participants, or C) usual care. For the outcomes not based on racial concordance, patients in arms A and B (the video arms) will be combined and compared with the usual care population. Study participants will be blinded to differences in the two videos.

Patient Population

Outpatient, self-identified black or African-American patients age 21 or older, with New York Heart Association class I–III heart failure who are eligible for an ICD.
Study Objectives

The primary objective is the decision for ICD implantation and the effect of racial concordance on the decision for ICD implantation.

The secondary objectives are:
- Changes in patient knowledge (pre- and post-intervention)
- Changes in decisional conflict (pre- and post-intervention)
- ICD receipt within 90 days of the decision for ICD implantation

In-depth qualitative interviews of 90 patient participants will focus on: a) knowledge of SCD and ICD therapy, b) influences on the decision to accept or decline an ICD, c) impact of the video on the decision, and d) barriers to ICD placement following the initial decision.

Study coordinators will assess the time patients spend with their provider in each arm of the study.

Duration of Study Participation
90 days

Study Centers
Approximately 12 U.S. sites

Sample Size
480 patients

Study Timelines
3 years, with enrollment ending in December 2018

Learn More
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