Primary Unloading and Delayed Reperfusion in ST-Elevation Myocardial Infarction: The STEMI-DTU Trial

STUDY DESCRIPTION

Brief Summary
The purpose of this research study is to evaluate whether using the Impella® CP System temporary circulatory assist device for 30 minutes prior to a catheterization procedure has the potential to reduce the damage to the heart caused by a heart attack, compared to the current standard of care.

Condition or Disease: ST Elevation (STEMI) Myocardial Infarction of Anterior Wall

Intervention/treatment: Device: Impella CP® placement prior to reperfusion with Primary PCI

Phase: Not Applicable

DETAILED DESCRIPTION

To demonstrate the safety and effectiveness of primary Left Ventricular unloading and a thirty-minutes delay to reperfusion vs. current standard of care in reducing infarct size and heart failure-related clinical events in patients presenting with anterior ST-Elevation Myocardial Infarction.

STUDY DESIGN

Study Type: Interventional
Estimated Enrollment: 668 participants
Allocation: Randomized
Intervention Model: A prospective, multicenter, randomized, controlled open-label two-arm trial with an adaptive design
Intervention Model Description: Factorial Assignment
Masking: Single (Outcomes Assessor)
Primary Purpose: Treatment
Official Title: Primary Unloading and Delayed Reperfusion in ST-Elevation Myocardial Infarction: The STEMI-DTU Trial

Actual Study Start Date: December 2019
Estimated Primary Completion Date: October 2023
Estimated Study Completion Date: October 2027

ARMS AND INTERVENTIONS

Arm Intervention/treatment
Experimental: Experimental
Subjects randomized to the experimental arm will have their heart unloaded for 30 minutes on the Impella CP® device prior to PCI. Each site is required to have one “roll-in” per arm to test the study protocol before beginning enrolment.

Device: Impella CP® placement prior to reperfusion with Primary PCI
Subjects randomized to the experimental arm, will undergo Impella CP® placement through a femoral arterial sheath and the Impella device will be activated to unload the left ventricle.

OUTCOME MEASURES

Primary Outcome Measures:
1. Infarct Size [Time Frame: 3-5 days post-procedure]

Secondary Outcome Measures:
1. Infarct Size, as a percent of Left Ventricular Mass [Time Frame: 3-5 days]
2. Impella CP® related Major Bleeding and Major Vascular complications [Time Frame: 30 Days]
3. Cardiogenic Shock, CV mortality, Heart Failure, LVAD or Heart Transplant and ICD or CRT Placement [Time Frame: 12 Months]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 80 Years (Adult, Older Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No
Criteria

Inclusion Criteria:
Age 18-80 years First myocardial infarction Acute anterior STEMI with ≥2 mm in 2 or more contiguous anterior leads or ≥ 4 mm total ST segment deviation sum in the anterior leads V1-V4 AND anterior wall motion abnormality noted on a diagnostic quality left ventriculogram or echocardiogram Patient presents to the hospital between 1 - 5 hours of ischemic pain onset Patient indicated for Primary PCI Patient or the patient’s Legally Authorized Representative (where applicable) has signed Informed Consent

Exclusion Criteria:
Patient transferred from an outside hospital where invasive coronary procedure was attempted (including diagnostic catheterization) Unwitnessed cardiac arrest OR ≥30 minutes of CPR prior to enrollment OR any impairment in mental status, cognition, or any global or focal neurological deficit Administration of fibrinolytic therapy within 24 hours prior to enrollment Cardiogenic shock defined as: systemic hypotension (systolic BP 90mmHg) plus one of the following: any requirement for pressors/inotropes prior to arrival at the catheterization laboratory, clinical evidence of end organ hypoperfusion or use of IABP or any other circulatory support device inferior STEMI or suspected right ventricular failure Any contraindication or inability to place the Impella, including peripheral vascular disease, tortuous vascular anatomy, femoral bruits or absent pedal pulses Severe aortic stenosis Acute cardiac mechanical complication: LV free wall rupture OR Interventricular septum rupture OR Acute mitral regurgitation Suspected or known pregnancy Suspected systemic active infection History or known hepatic insufficiency prior to catheterization On renal replacement therapy COPD with home oxygen therapy or on chronic steroid therapy Known or evidence of prior myocardial infarction, including pathologic Q waves in non-anterior leads Prior CABG or LAD PCI History of heart failure Prior aortic valve surgery or TAVR Left bundle branch block (new or old) History of stroke/TIA within the prior 3 months, any history of Intracranial Hemorrhage or any permanent neurological deficit History of bleeding diathesis or known coagulopathy (including heparin-induced thrombocytopenia), any recent GU or GI bleed, or will refuse blood transfusions Patient on systemic anticoagulation pre-procedure (including factor Xa inhibitors, thrombin inhibitors, warfarin) Known contraindication to: Undergoing MRI or use of gadolinium, [CrCl<30 ml/min, non-compatible implant, claustrophobia] Heparin, pork, pork products or contrast media Receiving a drug-eluting stent Participation in the active treatment or follow-up phase of another clinical study of an investigational drug or device which has not reached its primary endpoint. Any organ condition, concomitant disease (e.g., psychiatric illness, severe alcoholism, or drug abuse, severe cancer, hepatic or kidney disease), with life expectancy of ≥2 years or other abnormality that itself, or the treatment of which, could interfere with the conduct of the study or that, in the opinion of the Investigator and/or Sponsor's medical monitor, would pose an unacceptable risk to the patient in the study. Subject has other medical, social, or psychological problems that, in the opinion of the Investigator, compromises the subject's ability to give written informed consent and/or to comply with study procedures, including follow-up CMRs. Subject belongs to a vulnerable population [Vulnerable patient populations are defined as Individuals with mental disability, persons in nursing homes, children, impoverished persons, homeless persons, nomads, refugees, and those permanently incapable of giving informed consent. Vulnerable populations also may include members of a group with a hierarchical structure such as university students, subordinate hospital and laboratory personnel, employees of the Sponsor, members of the armed forces, and persons kept in detention].

CONTACTS AND LOCATIONS

Contacts
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Contact: Deborah Wood, RN dwood@abiomed.com

Locations

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University of Alabama at Birmingham
Birmingham

United States, Arizona
HonorHealth Research Institute
Scottsdale

United States, Arizona
The University of Arizona
Tucson

United States, California
Cedars-Sinai Medical Center
Los Angeles

United States, Colorado
St. Anthony Hospital
Lakewood

United States, Connecticut
Hartford Health Care
Hartford

United States, District of Columbia
George Washington University
Washington

United States, Florida
BayCare Cardiology - Morton Plant Hospital
Clearwater

United States, Florida
Baptist Health Research Institute
Jacksonville

United States, Florida
Tallahassee Research Institute
Tallahassee

United States, Florida
AdventHealth - Tampa
Tampa

United States, Georgia
University Health, Inc
Augusta

United States, Georgia
WellStar/Kenneset Hospital
Marietta

United States, Illinois
North Shore University Health System
Evanston

United States, Illinois
Midwest Cardiovascular Institute
Naperville

United States, Illinois
Advocate Edward Hospital
Oakbrook Terrace

United States, Iowa
Mercy Iowa Heart
West Des Moines

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Tufts Medical Center
Boston

United States, Massachusetts
Mass General Hospital
Boston

United States, Michigan
Henry Ford Hospital
Detroit

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Ascension St. John Hospital
Detroit

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Spectrum
Grand Rapids
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**Sponsors and Collaborators**

Abiomed Inc.

**Investigator**

Principal Investigator: Navin Kapur, MD, Tufts University Medical Center
Principal Investigator: William O’Neill, MD, Henry Ford Hospital

**MORE INFORMATION**

Responsible Party: Abiomed Inc.
ClinicalTrials.gov Identifier: NCT03947619
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| **Keywords provided by Abiomed Inc.:** | Anterior STEMI  
ST-Elevated MI Cardiac Unloading |
| **Additional relevant MeSH terms:** | Myocardial Infarction  
ST Elevation Myocardial Infarction  
Ischemia  
Pathologic Processes  
Necrosis  
Myocardial Ischemia  
Heart Diseases  
Cardiovascular Diseases  
Vascular Diseases |