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A multicenter, randomized, controlled study of mechanical left ventricular unloading with counterpulsation to reduce infarct size prepercutaneous coronary intervention for acute myocardial infarction: rationale and design of the Counterpulsation Reduces Infarct Size Acute Myocardial Infarction trial.

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Source

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Abstract

BACKGROUND:

Despite advances in care processes to improve reperfusion in patients with acute myocardial infarction (AMI), the short-term and 1-year mortality remains high, in part, because of reperfusion injury, microvascular obstruction, and infarct expansion. Intraaortic balloon counterpulsation (IABC) is an adjunct to revascularization and has reduced microvascular obstruction and infarct size in animal models of AMI.

METHODS:

CRISP AMI is a multicenter randomized trial that aims to determine if IABC initiated before percutaneous coronary intervention (PCI) for reperfusion compared with routine PCI in patients with anterior ST-segment elevation AMI reduces infarct size as measured by cardiac magnetic resonance imaging. Patients are randomly assigned to receive IABC initiated before primary PCI and continued for at least 12 hours or routine PCI with standard-of-care medical therapy in both groups. The primary efficacy end point is infarct size measured by cardiac magnetic resonance imaging at 3 to 5 days post-PCI. The secondary clinical end point is the composite of major adverse clinical events including death, reinfarction, and heart failure at 6 months. According to sample size calculation, 300 patients will be randomized at 50 sites across 10 countries.

CONCLUSION:

The CRISP AMI study will determine if IABC before reperfusion in patients with anterior AMI reduces infarct size.