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Philips Announces Completion of Patient Enrolment in Therapeutic Hypothermia Study

CHILL-MI study to further evaluate the safety and effectiveness of the InnerCool RTx endovascular cooling system to reduce reperfusion injury in acute ST-elevation myocardial infarction patients

Royal Philips Electronics announced on April 30, 2013, the completion of patient enrollment in the CHILL-MI clinical study designed to further evaluate the safety and effectiveness of the company's InnerCool RTx endovascular cooling system in patients with ST-elevation myocardial infarction (STEMI).

Following an acute myocardial infarction, restoring blood flow to the heart is critical to the survival of heart tissue.¹ However, this process may cause additional damage known as reperfusion injury.² Preventing heart tissue damage is a significant unmet medical need in the treatment of acute myocardial infarction. Endovascular cooling is a method for quickly achieving therapeutic hypothermia – reducing a patient's body temperature to help lower the amount of tissue injury.³

This prospective, randomized study enrolled 120 patients in nine European centers. Patients received immediate percutaneous coronary intervention (primary PCI) with or without adjunctive rapid endovascular cooling.

The primary endpoint of the study is reduction of myocardial infarct size as a percentage of myocardium at-risk, assessed by cardiac magnetic resonance imaging (MRI) at 4 days (\pm 2 days). Secondary safety and efficacy endpoints are also being evaluated. Principal investigators for the study are David Erlinge, MD PhD, Professor of Cardiology and Goran Olivecrona, MD PhD from the Department of Cardiology, Lund University in Lund, Sweden.

Previous research has shown that therapeutic hypothermia can reduce infarct size in patients whose body temperature reaches $\leq 35^{\circ}\text{C}$ prior to reperfusion or opening of the blocked artery. The previously published

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Rapid MI-ICE study, which utilized the InnerCool system, showed a 38 percent reduction in infarct size in STEMI patients who were cooled to a body temperature of $\leq 35^{\circ}\text{C}$ before primary PCI.⁴

"Therapeutic hypothermia is the most promising therapy to reduce infarct size in STEMI patients," says Dr. Erlinge. "We look forward to sharing the clinical experience of this innovative therapy as the results become available." Added Dr. Olivecrona, "Clinical sites were able to cool patients quickly and the cooling procedure was easily implemented into the workflow of the cardiac catheterization lab with minimal delay."

"We are very pleased to report completion of enrollment in the CHILL-MI study," said Randy Whitfield, Vice President, Therapeutic Care, at Philips Healthcare. "This would offer a new therapeutic option for acute myocardial infarction patients who are at risk for heart tissue damage due to reperfusion injury."

Acute myocardial infarction (AMI) is one of the leading causes of mortality, with STEMI being the most severe form of AMI. In the U.S. and Europe, the incidence of STEMI is 770-800 per million respectively.^{5,6} In hospital, mortality for STEMI patients ranges between 4.2-13.5 percent.^{7,8} Initiating percutaneous coronary intervention or primary PCI as early as possible is critical to the survival of heart tissue.

The Philips InnerCool RTx endovascular system cools patients from the inside out. A unique heat-exchange catheter with an integrated temperature sensor is positioned below the heart via the femoral vein and connected to a proprietary console. The closed-loop system rapidly cools the patient and monitors core body temperature without fluid introduction or exchange by circulating cool saline in the catheter.

The Philips InnerCool RTx endovascular cooling system is commercially available in the United States, but is limited by applicable law to investigational use for the treatment of myocardial infarction.

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