Trial evaluates safety and effectiveness of systemic therapeutic hypothermia in anterior STEMI

May 18 2021

Credit: Unsplash/CC0 Public Domain

Results of the interim analyses performed after 12 months in the first 111 patients enrolled in phase II Cool AMI trial evaluating safety and

effectiveness of systemic therapeutic hypothermia as an adjunctive therapy in anterior STEMI undergoing PCI as compared to PCI only. Analyses showed significant differences among treatment groups, including longer randomisation-to-balloon time and total ischemic time in treatment arm, justifying premature trial discontinuation.

Therapeutic mild systemic hypothermia, when achieved before reperfusion of the infarct related vessel, has shown to limit infarct size in experimental animal models. Despite encouraging initial in vivo results, several prior RCTs reported overall neutral effects. A potential advantage of hypothermia was detected in early presenters with anterior STEMI cooled prior to reperfusion.

Safety of this approach in anterior STEMI patients was initially tested in the COOL AMI EU pilot phase I trial, which results were previously presented at EUROPCR 2017 and published in Eurointervention.

The COOL AMI EU pivotal trial, is an industry initiated, multicenter, prospective, interventional, randomised-controlled phase II trial with a 1:1 randomisation protocol comparing systemic therapeutic hypothermia in patients with recent onset anterior STEMI (

Primary efficacy endpoint was set as a relative reduction of 20% in mean anterior myocardial infarct size (as % left ventricular mass) determined by cardiac magnetic resonance imaging at 4-6 days post-infarct in the cooling + PCI arm as compared to the PCI only arm.

The secondary safety endpoint was defined as a composite of cardiac death, myocardial infarction and clinically-indicated target lesion revascularization at 30 day follow-up. According to the statistical analysis plan, 500 patients were expected to be enrolled to detect a relative reduction of 20% in mean infarct size in the treatment group. Interim analyses were pre-specified as per protocol.

During the LBT sessions of the upcoming EUROPCR 2021 congress, results of the interim analyses performed at 12 months after enrolment of 111 patients (58 treatment arm, 52 controls) were presented by Dr. M Noc (Ljubljana, Slovenia). The interim analysis led to premature, sponsor promoted, trial discontinuation.

Trialists observed significant differences among treatment groups, including longer randomisation-to-balloon time (61±21 vs 32±18 minutes, p