
Trial Designs

Rationale and design of the Statins Evaluation in Coronary procedUres and REvascularization: The SECURE-PCI Trial

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Abstract

Background

Previous evidence suggests that acute treatment with [statins](#) reduce atherosclerotic complications, including periprocedural [myocardial infarction](#), but currently, there are no large, adequately powered studies to define the effects of early, high-dose statins in patients with [acute coronary syndrome](#) (ACS) and planned invasive management.

Objectives

The main goal of Statins Evaluation in Coronary procedUres and [REvascularization](#) (SECURE-PCI) Trial is to determine whether the early use of a loading dose of 80 mg of [atorvastatin](#) before an intended [percutaneous coronary intervention](#) followed by an additional dose of 80 mg 24 hours after the procedure will be able to reduce the rates of major [cardiovascular events](#) at 30 days in patients with an ACS.

Design

The SECURE-PCI study is a pragmatic, multicenter, double-blind, [placebo-controlled](#) randomized trial planned to enroll around 4,200 patients in 58 different sites in Brazil. The primary outcome is the rate of *major cardiovascular events* at 30 days defined as a composite of all-cause mortality, nonfatal acute myocardial infarction, nonfatal stroke, and coronary revascularization.

Summary

The SECURE PCI is a large randomized trial testing a strategy of early, high-dose statin in patients with ACS and will provide important information about the acute treatment of this patient population.

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