



CLEAR SYNERGY (OASIS 9)

Colchicine and spironolactone in patients with myocardial infarction who have undergone PCI/SYNERGY Stent Registry – Organization to Assess Strategies of Ischemic Syndromes 9

Introduction

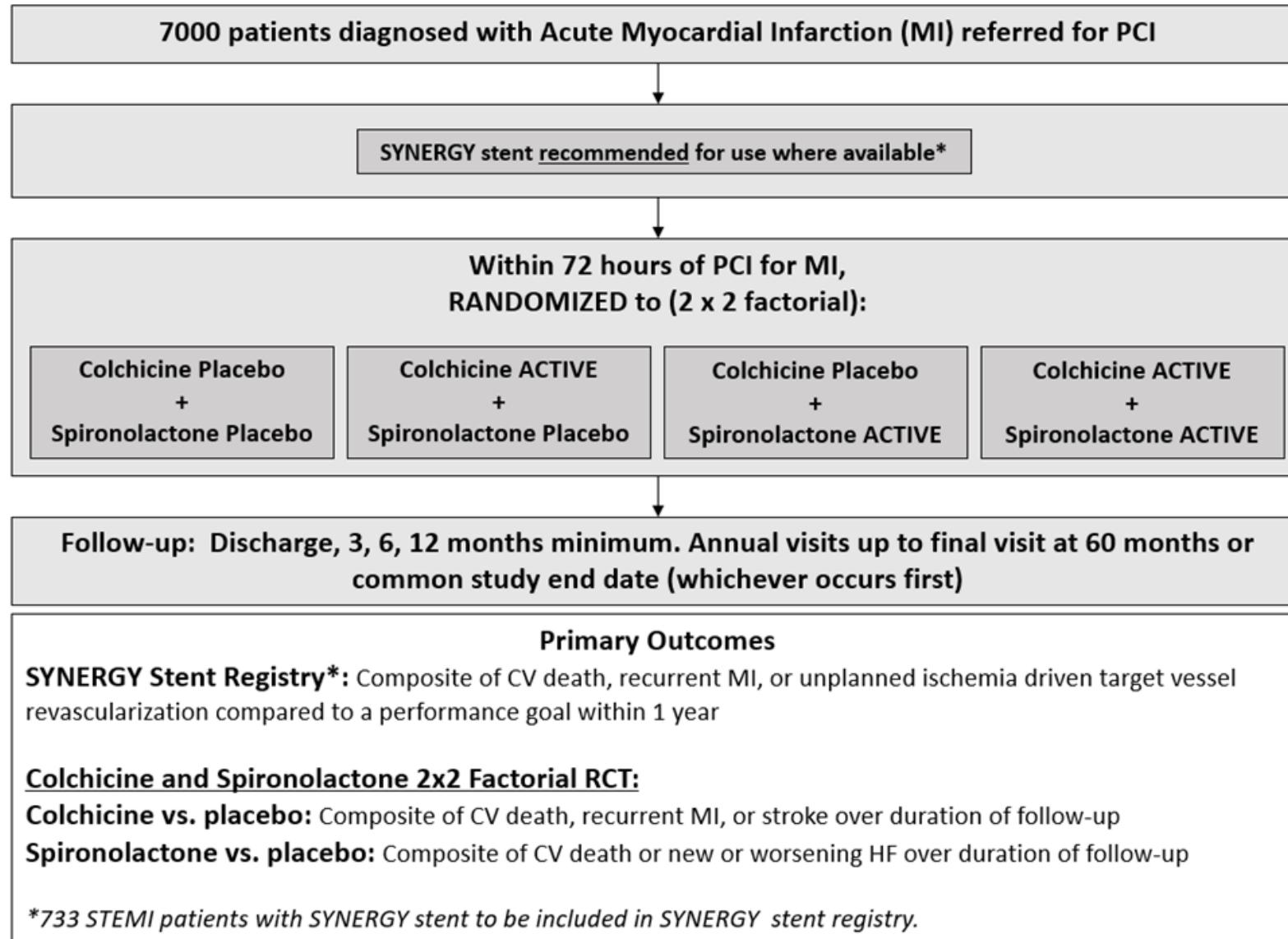


The CLEAR SYNERGY (OASIS 9) trial pairs a SYNERGY stent registry with an RCT to test 2 inexpensive generic medications to evaluate if routine administration in MI is clinically effective for the reduction of cardiac outcomes

- ▶ Colchicine
 - ▶ Inflammation is important in plaque rupture and infarct remodeling, so by reducing it may improve outcomes
- ▶ Spironolactone
 - ▶ Several studies have shown that adding an aldosterone antagonist to standard therapy (including ACE inhibitors, beta-blockers and diuretics) effectively reduced mortality rates in patients with heart failure or MI accompanied by heart failure.

Both colchicine and spironolactone are low cost generic drugs that could have a significant impact on post-PCI outcomes if effective.

Study Flow Diagram



Study Hypothesis



Colchicine and Spironolactone 2x2 Factorial RCT

1. Colchicine will reduce cardiovascular death, recurrent myocardial infarction (MI), and stroke
2. Spironolactone will reduce cardiovascular death and new or worsening heart failure

SYNERGY Registry

1. The SYNERGY stent will be non-inferior to historical performance goal for MACE in STEMI