



CLEAR SYNERGY

# 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

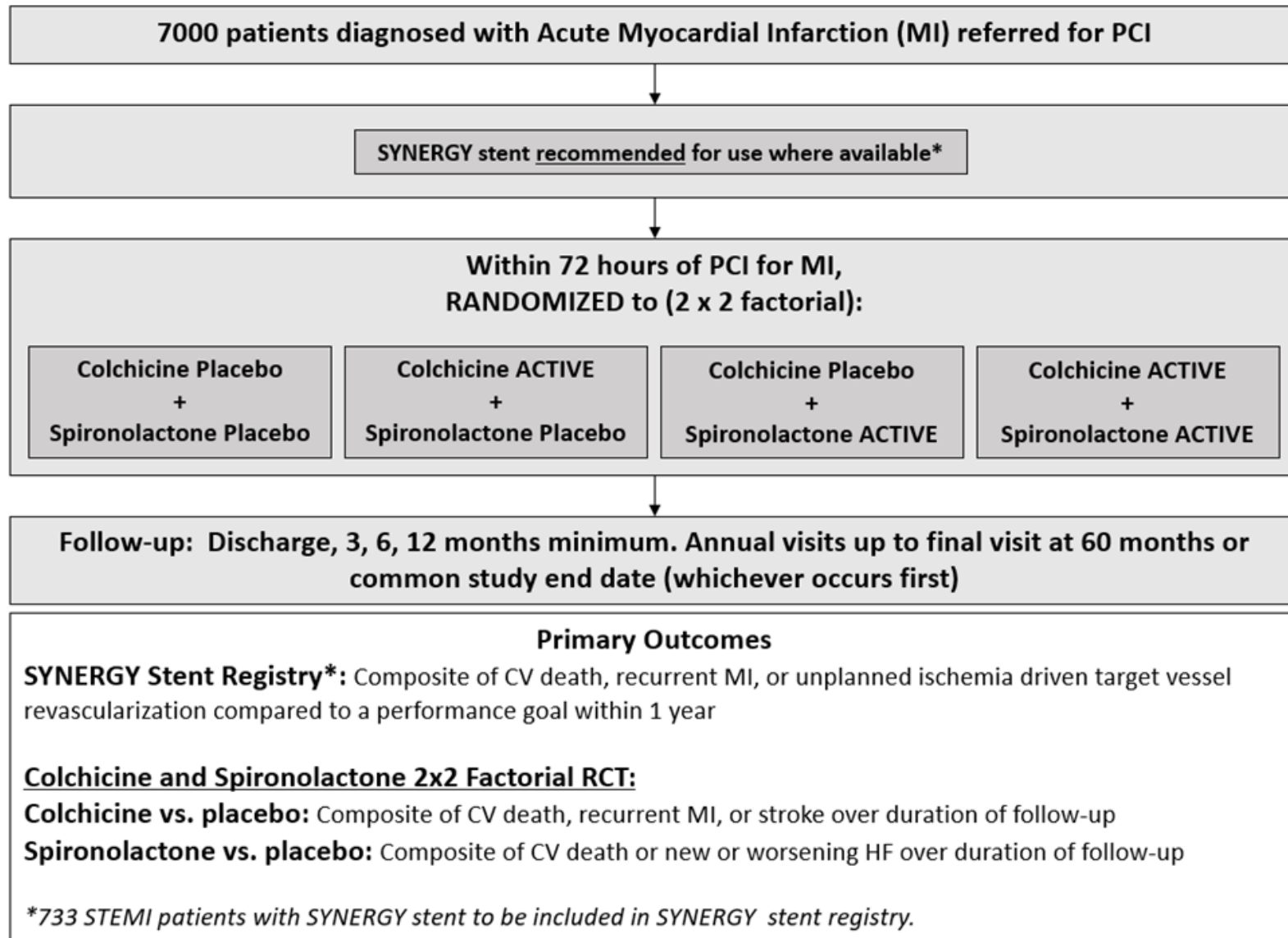


The CLEAR SYNERGY (OASIS 9) trial pairs a SYNERGY stent registry with an RCT to test 2 inexpensive generic medications to evaluate if routine administration in MI is clinically effective for the reduction of cardiac outcomes

- ▶ 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