

A Large International Trial Assessing the Effects of Clonidine on Major Arterial Events Patients Undergoing Noncardiac Surgery – POISE 2 Trial

Purpose: Major non-cardiac surgeries predispose to vascular complications (e.g. vascular death, nonfatal heart attack due to activation of the sympathetic system), nonfatal cardiac arrest, or nonfatal stroke) common after these surgeries and represent a problem in this surgical group.

Questions to answer: Can clonidine given during and after non-cardiac surgeries (with or at risk of atherosclerotic disease) prevent vascular complications such as MI without compromising blood pressure?

Trial Design	2 X 2 Factorial design, randomized controlled, double blind study. Patients were assigned to one of four groups) ASA + clonidine, ASA + clonidine placebo, ASA placebo + clonidine, or ASA placebo + clonidine placebo. The Clonidine arm results are reported here; 0.2mg Clonidine was used in this study. (ASA results are reported separately)				
Primary Endpoint	Composite of death and adjudicated MI at 30 day in non-cardiac surgery patients				
Trial Results		Clonidine	Placebo	Hazard Ratio (95%)	P value
	Primary Outcome Death or MI Events	N= 5009 367 (7.3)	N=5001 339 (6.8)	1.08 with clonidine (0.93-1.26)	0.29

Take Away - Clonidine does not decrease postop non-fatal MI or death. Clonidine should not be given to patients having noncardiac surgery in an effort to reduce perioperative mortality or MI. In the clonidine arm, there was clinically important hypotension in 2,385 patients (48%) vs. 1,854 placebo (37%).