

Steroids In caRdiac Surgery Trial (SIRS)

Background: Cardiopulmonary bypass (CPB) causes systemic inflammatory responses (cell and protein) that can cause the development of post-operative complications. Steroids have been shown to reduce the body's response to the inflammatory process during and following the use of cardiopulmonary bypass.

Questions to answer: Will the using 250mg of IV methylprednisolone given once during anesthetic induction and once during CPB initiation result in improved early survival and fewer MI in higher risk cardiac surgery patients needing CPB?

Trial Design	Randomized, double-blind, international, multicenter, parallel assignment of either methylprednisolone (500 mg) or matching placebo. N=7500 patients with a high EuroSCORE (>6), undergoing cardiopulmonary bypass during surgery.			
Primary Endpoint	30 Day mortality all cause mortality (secondary outcome was composite death, MI, stroke, renal failure or respiratory failure within 30 days).			
Trial Results Primary Endpoint	Steroid (n-3755) 4.1%	Placebo (n-3752) 4.7%	Relative Risk 0.88 (0.71-1.09)	P-Value 0.23
Secondary Endpoint MI/Death	Steroid (n-3755) 16.5%	Placebo (n-3752) 14.3%	Relative Risk 1.16 (1.04-1.29)	P-Value 0.008

Take Away: Steroids should not be given prophylactically during cardiac surgery in those patients requiring CBP as it does not reduce death at 30 days in this group. Secondary analysis showed that methylprednisolone increased the risk of early MI in the peri-op period.