

RED-CABG

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Sponsor:

Schering-Plough Research Institute, a Division of Schering Corporation

Study Purpose:

The Effect Of Acadesine On Clinically Significant Adverse Cardiovascular and Cerebrovascular Events In High-Risk Subjects Undergoing Coronary Artery Bypass Graft (CABG) Surgery Using Cardiopulmonary Bypass (Protocol No. P05633): **RED-CABG Trial (R**eduction in Cardiovascular **E**vents by Aca**D**esine in Subjects Undergoing **CABG**)

Objective:

To evaluate the clinical benefit of acadesine in reducing the incidence of ischemia-reperfusion injury resulting from coronary artery bypass graft (CABG) surgery, as measured by the first occurrence of any component of the composite primary endpoint of all-cause death, severe left ventricular dysfunction (SLVD), or non-fatal stroke occurring during or following CABG surgery through postoperative day (POD) 28.

Inclusion Criteria:

- A high risk patient undergoing non emergency CABG surgery requiring CPB and cardioplegia.
- Age: ≥ 50 years
- At least one of the following risk factors:
 - Female (but not pregnant or lactating), or
 - History of prior CABG, or
 - History of myocardial infarction (MI), or
 - History of ischemic stroke, or
 - Left ventricular ejection fraction $\leq 30\%$, or
 - Diabetes mellitus requiring insulin and/or antidiabetic agents.
- Significant coronary artery stenosis

Exclusion Criteria:

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- Planned valve replacement, carotid artery or aortic surgery, distal coronary endarterectomy, surgical ablation for cardiac arrhythmia, or ventricular aneurysmectomy, alone or with CABG surgery (repair for mild to moderate mitral valve disease with concomitant CABG is not excluded).
- Planned or staged major surgery within 30 days of CABG surgery
- CABG surgery using intermittent aortic cross clamping without cardioplegia.
- Minimally invasive surgery (ie, without use of CPB).
- MI within 5 days prior to surgery.
- Pre-operative or planned intra operative/postoperative use of intra-aortic balloon pump (IABP), ventricular assist device (VAD), extra-corporeal membrane oxygenator (ECMO), or other mechanical hemodynamic assist device.
- History or presence of gout or uric acid nephrolithiasis.
- Serum creatinine >2 mg/dL (180 µmol/L).
- Serum alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >2 x Upper Limit of Normal (ULN).
- Adenosine, aminophylline, nicotinic acid, pentoxifylline, theophylline, and any cardioplegia solution containing adenosine, dipyridamole, lidoflazine, or lidocaine within 24 hours before surgery:
- Dipyridamole within 2 days and allopurinol or febuxostat within 4 days before surgery
- Food and drinks containing caffeine, theobromines or methylxanthines (such as coffee, tea, colas, some 'energy' drinks or chocolate) within 12 hours before surgery.
- Pregnancy

Status:

Active enrollment

If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.