

Efficacy and Safety of 4F-PCC (4-Factor Prothrombin Complex Concentrate) in Adult Patients Undergoing Complex Cardiovascular Surgery With Cardiopulmonary Bypass (CPB)

NCT07094087

Status	RECRUITING
Phase	Phase 3
Sponsor	CSL Behring
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (5)

- Adult greater than or equal to (e) 18 years and has provided written informed consent.
- Undergoing elective complex cardiovascular surgery requiring CPB, including procedures of the thoracic aorta (with or without additional cardiac interventions), aortic valve replacement + coronary artery bypass graft (CABG), complex valve surgeries, mitral valve repair + CABG, and mitral valve replacement + CABG and reoperative CABG. Reoperative procedures are permitted. Excluded surgeries are as follows: heart transplantation, insertion or removal of ventricular assist devices (except for intra-aortic balloon pumps), and acute repair of thoracoabdominal aneurysms.
- Coagulation factor replacement (ie, 4F-PCC or FFP) is ordered in the operating room for the management of bleeding, in accordance with accepted clinical standards. The following criteria must be met:
- INR e 1.6 (point-of-care INR testing by Hemochron e 5 to 10 minutes after protamine infusion for heparin reversal). If a participant needs a second dose of protamine, a new INR measurement should be performed to confirm eligibility.
- Significant microvascular hemorrhage (ie, not due to surgical complications), as defined by a BSS score of e 2.

Exclusion (1)

- Administration of any systemic hemostatic therapy, such as cryoprecipitate, platelets, FFP, PCC (eg, 4-factor / 3-factor PCC \[4F-PCC / 3F-PCC\]), Factor VIII (FVIII) inhibitor bypassing activity (FEIBA), recombinant activated Factor VIIa (rFVIIa), or other coagulation factor products, in the 24 hours before study surgery, except when FFP is added to the CPB circuit.

Locations (19 total)

UCLA Health - Ronald Reagan Medical Center, Los Angeles, California, United States
University of Chicago Medicine, Chicago, Illinois, United States
University of Maryland Medical Center (UMMC), Baltimore, Maryland, United States
... and 16 more locations