

Efficacy of Prothrombin Complex Concentrate Reducing Perioperative Blood Loss in Cardiac Surgery

NCT04244981

Status	RECRUITING
Phase	Phase 4
Sponsor	SHI Jia
Enrollment	820 participants

Key Eligibility Criteria

Inclusion (4)

- Age between 18 and 80 years.
- Undergoing elective coronary artery bypass grafting (CABG) or valve replacement or valvuloplasty through CPB.
- Signing of the informed consent form.
- Developing coagulation factor deficiency or coagulopathic bleeding during the surgery, meeting the indications of PCC or FFP treatment: a) prolonged APTT (> 45 s) measured 20 minutes after CPB, and b) excessive bleeding observed.

Exclusion (8)

- History of cardiac surgery.
- Severe hepatic dysfunction before surgery.
- Coagulopathy before surgery, including inherited or acquired coagulation factor deficiencies, thrombocytopenia, platelet dysfunction and other bleeding disorders.
- Use of warfarin and INR > 1.2 before surgery.
- Withdrawal of clopidogrel less than 5 days and low molecular weight heparin less than 12 hours before surgery.
- ... and 3 more (see full listing online)

Locations (2 total)

Cardiovascular Institute and Fuwai Hospital, CAMS&PUMC, Beijing, Beijing Municipality, China
Peking Union Medical College Hospital, Beijing, Beijing Municipality, China