

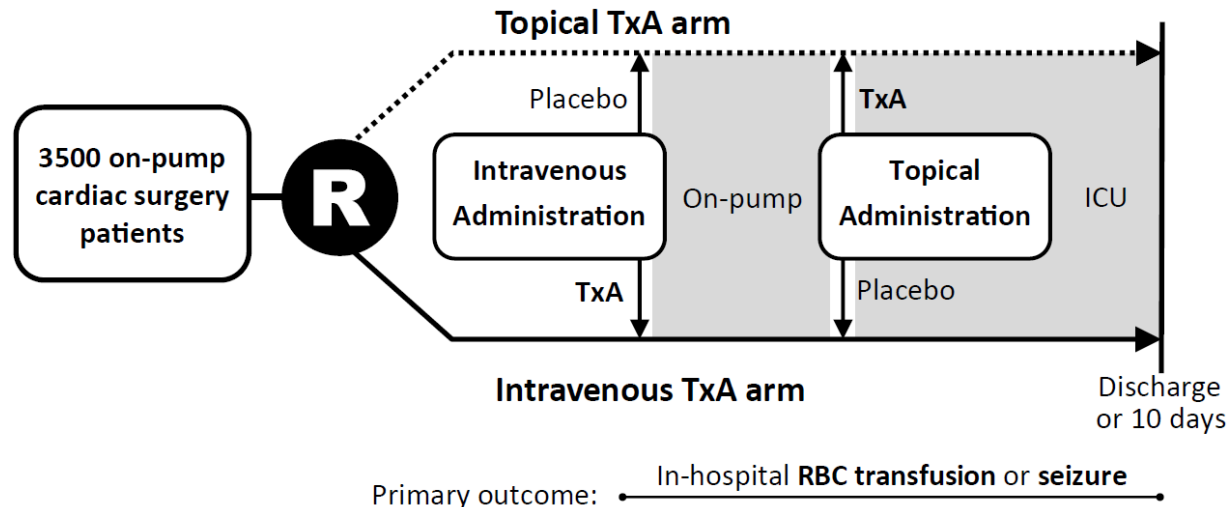


Decreasing Postoperative Blood Loss by  
Topical vs. Intravenous Tranexamic Acid in  
Open Cardiac Surgery

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# Design

- Investigator-initiated, multi-centre, double-dummy, randomized controlled trial
- 3500 on-pump cardiac surgery patients
- Participants followed in-hospital until discharge or 10 days (whichever occurs first)



# Interventions

## **Topical Tranexamic Acid (TxA) IV placebo + topical TxA during surgery:**

- Topical TxA: 5 to 10 g TxA (50 to 100 mL) poured into the pericardial and mediastinal cavities after protamine administration
- Intravenous Placebo: 10 to 100 mL of saline in place of TxA administered intravenously as per standard care at the beginning and during surgery

## **Intravenous Tranexamic Acid (TxA) IV TxA + topical placebo at the beginning and during surgery:**

- Intravenous TxA: 1 to 10 g TxA (10 to 100 mL) administered intravenously as per standard care. The dose typically varies from 3 to 6 g TxA per patient
- Topical Placebo: 50 to 100 mL of saline poured into the pericardial and mediastinal cavities after protamine administration

# Eligibility

## Inclusion Criteria

- $\geq 18$  years of age undergoing a cardiac surgical procedure (i.e. isolated CABG, isolated single cardiac valve surgery or a combination of both or isolated ascending aorta replacement) with the use of cardiopulmonary bypass (CPB) and median sternotomy

## Exclusion Criteria

- Allergy to tranexamic acid
- Undergoing minimally invasive surgery
- Fulfill any of the following transfusion risk factors (A-D):
  - A. Emergency surgery
  - B. History of bleeding disorder
  - C. Inherited thromboembolic or hemorrhagic disease
  - D. Infective endocarditis (active)
- History of previous cardiac surgery
- Severe renal impairment (serum creatinine  $>250$   $\mu\text{mol/L}$ )
- Pre-operative hemoglobin  $<120$  g/L
- Expected circulatory arrest

# Outcomes

## Primary Outcome:

The composite of patients receiving in-hospital red blood cell transfusion or experiencing a seizure

## Secondary Outcome:

The individual components of the primary outcome

## Tertiary Outcomes:

- Blood product transfusions (as a composite and individually)
- Re-operation for bleeding or tamponade
- Duration of ICU stay
- MACE (composite of death, non-fatal MI and non-fatal stroke)