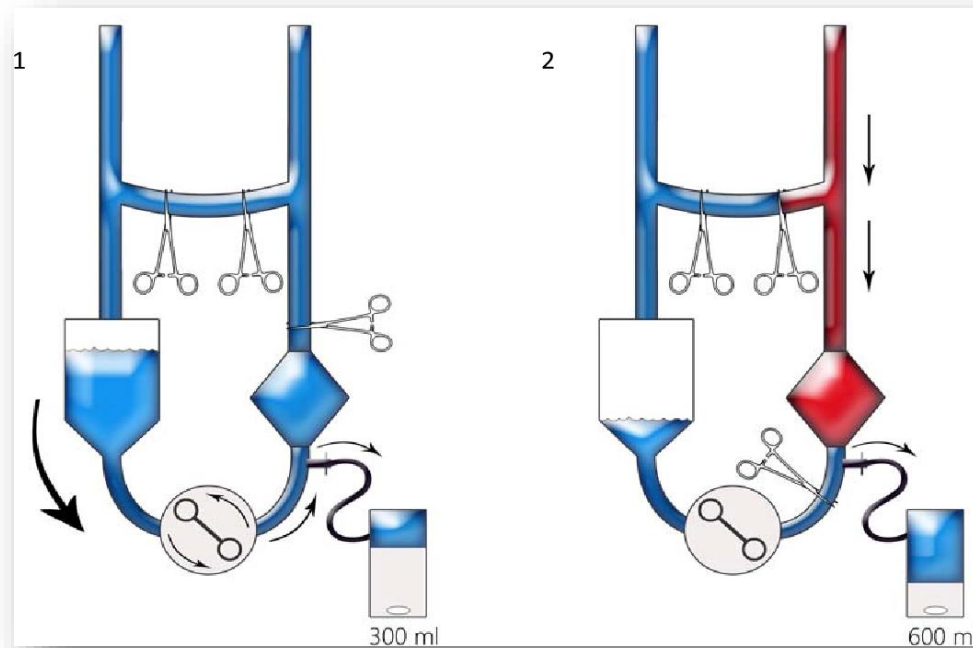


The effect of retrograde autologous priming on transfusion requirements after cardiac surgery (TheRAPy)

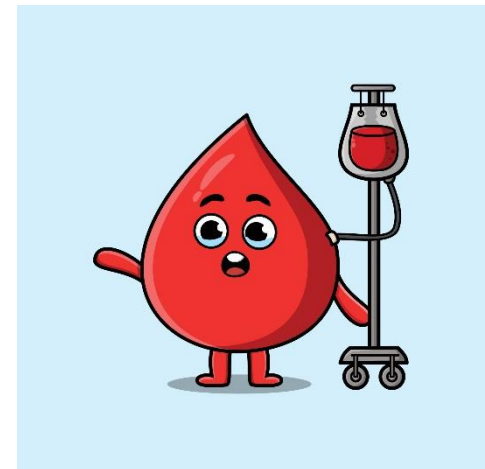
Background of Retrograde Autologous Priming (RAP)

- RAP is a simple and low-cost technique, whereby the patient's own blood, rather than crystalloid fluid, is used to prime the cardiopulmonary bypass (CPB) circuit



Background of Retrograde Autologous Priming (RAP)

- RAP may minimize hemodilution during cardiac surgery, a potentially modifiable contributor to red blood cell (RBC) transfusion
 - Lowering blood transfusions can decrease costs and resource use at the level of the healthcare system, and morbidity and mortality at the level of the individual patient
- There is a large variation in the clinical uptake of RAP, which reflects the limitations in existing evidence



Study Summary



Vanguard Objective: to assess the feasibility of a full-scale trial to determine whether an institutional policy of routine RAP versus a policy of crystalloid priming reduces intra- and post-operative RBC transfusion up to 72 hours after cardiac surgery

Study Design: Multi-centre, multiple period, cluster randomized crossover trial



Study Summary (cont.)

Intervention: 2 hospital-based policies for the initiation of CPB during cardiac surgery

1. RAP
2. Crystalloid Priming

Duration

- 12 x 4-week crossover periods

Sample Size

- Vanguard: 4,500 patients across 4 sites
- Full Trial: 16,800 patients across 20 sites



Description of the Policies

Routine RAP Policy (intervention)	Crystalloid Priming Policy (control)
<ul style="list-style-type: none">I. Use of arterial and venous autologous CPB priming in all adult patients undergoing cardiac surgery (minimum 300mL)II. Crystalloid priming acceptable for patients with a contraindication to RAP ($\leq 10\%$ expected; hemodynamic instability, need for emergency implementation of CPB) according to clinician discretion.	<ul style="list-style-type: none">I. Use of crystalloid priming in all patients undergoing cardiac surgeryII. RAP acceptable in patients with a contraindication to crystalloid priming ($\leq 10\%$ expected); refusal to receive transfusion, patients with rare blood types) according to clinician discretion



Primary and Secondary Outcomes

Phase	Primary Outcome(s)	Secondary Outcome(s)
Vanguard	<ul style="list-style-type: none"> Feasibility of the trial protocol, defined as adherence $\geq 90\%$ to both institutional policies applied in random sequence 	<ul style="list-style-type: none"> To collect data about critical parameters that affect the design and implementation of the full-scale trial
Full Trial	<ul style="list-style-type: none"> The mean number of RBC units transfused within 72 hours of cardiac surgery per patient in each centre 	<ul style="list-style-type: none"> The mean number of RBC units transfused in-hospital up to 30-days Incidence of transfusion at 72 hours and in-hospital up to 30-days Incidence of acute kidney injury (AKI) at 72 hours and in-hospital up to 30-days ICU and hospital length-of-stay In-hospital mortality Healthcare costs