EVALUATION OF A CLOSED LOOP BLOOD SAMPLING SYSTEM IN INTENSIVE CARE: A PILOT RANDOMISED CONTROLLED TRIAL. THE ENCLOSE TRIAL

Introduction: Management of critically ill patients involves extensive diagnostic testing and procedures to inform clinical decision making. This is commonly facilitated by an arterial catheter (AC) connected to a pressurised administration set that maintains patency and facilitates continuous monitoring. Blood sampling is enabled via this system but can result in blood wastage and contamination.

Objectives: To test the feasibility of conducting a randomised controlled trial (RCT) to evaluate the impact of a closed-loop blood sampling system and conservation bundle.

Methods: Single site, parallel group, pilot RCT comparing open system sampling (OS) to closed system sampling (CS) and conservation bundle aligned with national guidelines. Participants were ≥18 years who had AC inserted in intensive care. Randomisation was generated by statistician and then via opaque envelopes. Key outcomes included trial feasibility, blood sample loss, haematocrit (HCT) change, and transfusion (PRBC) use.

Results: 80 patients were randomised (n=39 OS group, n=41 CS group). Characteristics in each group were equal at baseline with overall mean age 60 years [SD 48.6-70.4], 58% male, and mean APACHE score 16 [SD 11-22]. The proportion of patients eligible was 29% and missed eligible 65%. Otherwise, feasibility criteria met with proportion of eligible patients agreeing to enrolment 99%, 100% of patients receiving allocated treatment and only 1% data missing. Analysis demonstrated a significant reduction in daily blood sample losses (OS 32.7(SD 1.58) mLs vs CS 15.5(SD 5.79) mLs, $t=8.454$, $df=78$, $p<0.001$). There was no significant difference in HCT levels. Daily PRBC use was less in the CS group (5%) vs 11% in OS group, though not significantly different.

Conclusions: A large, multi-site trial is feasible with enhanced eligibility criteria, increased recruitment support, and using a cluster design. The intervention reduced daily blood sample volumes and PRBC use. A hybrid effectiveness-implementation trial is planned to confirm above findings.