

Abstract:

Introduction: Peripherally inserted central catheters (PICCs) are vital for the delivery of medical therapies, but up to 30% of PICCs are associated with complications such as deep vein thrombosis or infection. The integration of antimicrobial and hydrophobic catheter materials, and pressure-activated valves, into polyurethane PICCs are innovations designed to prevent infective and/or thrombotic complications.

Methods and analysis: A multicentre, parallel group, superiority randomised controlled trial with two experimental arms ((1) hydrophobic PICC (with pressure-activated valve); (2) chlorhexidine gluconate-impregnated PICC (with external clamp)) and one control group ((3) conventional polyurethane PICC (with external clamp)). Recruitment of 1098 adult and paediatric patients will take place over 2 years at three tertiary-referral hospitals in Queensland, Australia. Patients are eligible for inclusion if their PICC is to be inserted for medical treatment, with a vascular size sufficient to support a 4-Fr PICC or larger, and with informed consent. The primary outcome is PICC failure, a composite of thrombotic (venous thrombosis, breakage and occlusion) and infective complications (PICC-associated bloodstream infection and local infection). Secondary outcomes include: all-cause PICC complication; thrombotic complications; infective complications; adverse events (local or systemic reaction); PICC dwell time; patient/parent satisfaction; and healthcare costs. Differences between both intervention groups and the control group will be compared using Cox proportional hazards regression. Effect estimates will be presented as HRs with corresponding 95% CI.

Ethics and dissemination: Ethical approval from Queensland Health (HREC/QCHQ/48682) and Griffith University (Ref. No. 2019/094). Results will be published.

Trial registration number: ACTRN12619000022167.

Reference:

Ullman AJ, August D, Kleidon T, Walker R, Marsh NM, Bulmer A, Pearch B, Runnegar N, Schults JA, Leema J, Lee-Archer P, Biles C, Southam K, Gibson V, Byrnes J, Ware RS, Chopra V, Coulthard A, Mollee P, Rickard CM, Harris PNA. Peripherally Inserted Central catheter iNnovation to reduce Infections and Clots (the PICNIC trial): a randomised controlled trial protocol. *BMJ Open*. 2021 Apr 14;11(4):e042475. doi: 10.1136/bmjopen-2020-042475. PMID: 33853797.

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