



The study aim is to determine the efficacy, cost-utility and acceptability to patients and professionals of an integrated PIVC system compared with a non-integrated PIVC system” Castillo et al (2018).

Abstract:

INTRODUCTION: Peripheral intravenous catheters (PIVCs) are frequently used in hospitals. However, PIVC complications are common, with failures leading to treatment delays, additional procedures, patient pain and discomfort, increased clinician workload and substantially increased healthcare costs. Recent evidence suggests integrated PIVC systems may be more effective than traditional non-integrated PIVC systems in reducing phlebitis, infiltration and costs and increasing functional dwell time. The study aim is to determine the efficacy, cost-utility and acceptability to patients and professionals of an integrated PIVC system compared with a non-integrated PIVC system.

METHODS AND ANALYSIS: Two-arm, multicentre, randomised controlled superiority trial of integrated versus non-integrated PIVC systems to compare effectiveness on clinical and economic outcomes. Recruitment of 1560 patients over 2 years, with randomisation by a centralised service ensuring allocation concealment. Primary outcomes: catheter failure (composite endpoint) for reasons of: occlusion, infiltration/extravasation, phlebitis/thrombophlebitis, dislodgement, localised or catheter-associated bloodstream infections.

SECONDARY OUTCOMES: first time insertion success, types of PIVC failure, device colonisation, insertion pain, functional dwell time, adverse events, mortality, cost-utility and consumer acceptability. One PIVC per patient will be included, with intention-to-treat analysis. Baseline group comparisons will be made for potentially clinically important confounders. The proportional hazards assumption will be checked, and Cox regression will test the effect of group, patient, device and clinical variables on failure. An as-treated analysis will assess the effect of protocol violations. Kaplan-Meier survival curves with log-rank tests will compare failure by group over time. Secondary endpoints will be compared between groups using parametric/non-parametric techniques.

ETHICS AND DISSEMINATION: Ethical approval from the Royal Brisbane and Women's Hospital Human Research Ethics Committee (HREC/16/QRBW/527), Griffith University Human Research Ethics Committee (Ref No. 2017/002) and the South Metropolitan Health Services Human Research Ethics Committee (Ref No. 2016-239). Results will be published in peer-reviewed journals.

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Full Text

Reference:

Castillo, M.I., Larsen, E., Cooke, M., Marsh, N.M., Wallis, M.C., Finucane, J., Brown, P., Mihala, G., Carr, P.J., Byrnes, J., Walker, R., Cable, P., Zhang, L., Sear, C., Jackson, G., Rowsome, A., Ryan, A., Humphries, J.C., Sivyer, S., Flanigan, K. and Rickard, C.M. (2018) Integrated versus non-integrated Peripheral intravenous catheter. Which Is the most effective system for peripheral intravenous catheter Management? (The OPTIMUM study): a randomised controlled trial protocol. *BMJ Open*. 8(5), p.e019916.

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