

The selection of the type of vascular access for haemodialysis is an important intervention question. However, only observational studies are available to inform decision-making in this area, and they are at high risk of selection bias” Quinn and Ravani (2016).

Abstract:

INTRODUCTION: The selection of the type of vascular access for haemodialysis is an important intervention question. However, only observational studies are available to inform decision-making in this area, and they are at high risk of selection bias. While a clinical trial comparing the effects of the 2 most frequently chosen strategies for haemodialysis access (fistulas and catheters) on patient important and ‘hard’ clinical end points is needed, the feasibility of such a trial is uncertain.

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METHODS AND ANALYSIS: This open-label pilot randomised controlled trial will test the feasibility and safety of randomising elderly people (≥ 65 years) who start haemodialysis with a central venous catheter (the most common initial type of haemodialysis access), and are eligible to receive a fistula, to a catheter-based strategy (comparator) or to a fistula-based strategy (intervention). We will enrol 100 patients at 10 centres across Canada. Participants assigned to the catheter-strategy arm will continue to use catheters; participants assigned to the fistula-strategy arm will receive a surgical attempt at fistula creation. The inclusion criteria are designed to minimise the risk of protocol violation and attrition. The primary outcome is feasibility, which we will assess by measuring: (1) the proportion of participants deemed eligible for the trial who consent to randomisation; and (2) the proportion of participants randomised to the intervention who receive the fistula surgery within 90 days of randomisation. Secondary outcomes will include safety outcomes, the reasons people and healthcare providers may not accept randomisation, and the reasons sites may not adhere to the trial protocol.

ETHICS AND DISSEMINATION: The Conjoint Health Research Ethics Board at the

University of Calgary approved the study protocol. We will submit the results of this feasibility study in a peer-reviewed journal.

TRIAL REGISTRATION NUMBER: NCT02675569, Pre-results.

Reference:

Quinn, R. and Ravani, P. (2016) ACCESS HD pilot: A randomised feasibility trial Comparing Catheters with fistulas in Elderly patients starting haemodialysis. *BMJ Open*. 6(11), p.e013081.

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