

Rethinking Access for Dialysis in Older People: Proposed Study Design

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Background

The arteriovenous fistula is widely regarded as the best long-term haemodialysis access, due to fewer complications and longer patency, whereas tunnelled catheters have traditionally provided temporary access when emergency dialysis is required, or when a fistula has not been successful. However, the dialysis access landscape has changed with older and more comorbid patients making up a greater proportion. These patients have both poorer fistula outcomes and shorter life expectancy, and whilst fistula formation is still desirable it may be less tolerable. Catheters are increasingly advocated as a long-term access option for some older and more comorbid patients. A randomised controlled trial has never been carried out comparing a fistula to a tunnelled dialysis catheter in the older haemodialysis population.

Research Question

What is the optimal design for a randomised study comparing different vascular access strategies (catheters vs. arteriovenous fistulae) in elderly patients expecting to start haemodialysis?

Aims & Objectives

By performing a pilot randomised controlled trial we aim to meet the following objectives:

1. Optimise study design by establishing the willingness of patients to participate and the protocol drop-out rates in the two treatment arms.
2. Determine the best validated questionnaires to measure differences in quality of life between the two treatment arms.
3. Assess staff acceptability and provide reassuring early data for the wider community.

Research Design

This study is an open label randomised controlled trial with a short follow-up period, intended as a pilot for a subsequent larger study, to answer key design issues.

We will include patients aged over 70, with declining kidney function and expecting to start haemodialysis within 6 to 12 months. Patients will be randomised in a 1:1 ratio to the fistula or catheter treatment group: the fistula group will be referred for fistula formation within 3 months of randomisation and the catheter group will have a line inserted when dialysis is required. We aim to recruit 52 patients, 26 in each treatment arm, over an 8-month period.

Data & Analysis

Patients will be followed for a minimum of 12 months. The primary outcomes will be

1. The willingness of patients to be randomised to either a fistula or a catheter.
2. The study drop-out rate as defined in the fistula group as failure to achieve a fistula attempt within 3 months of randomisation.

The secondary outcomes to be observed in this study include mortality, unplanned admissions, quality of life measurements and dialysis initiation. Data collection will be performed using electronic patient records and clinical correspondence.