

“Patients with end-stage renal disease needing urgent vascular access therefore traditionally require insertion of a tunnelled central venous catheter (TCVC). TCVCs are associated with high infection rates and central venous stenosis” Aitken et al (2015).

Reference:

Aitken, E., Geddes, C., Thomson, P., Kasthuri, R., Chandramohan, M., Berry, C. and Kingsmore, D. (2015) Immediate access arteriovenous grafts versus tunnelled central venous catheters: study protocol for a randomised controlled trial. *Trials*. 16(1), p.42.

Abstract:

**BACKGROUND:** Autologous arteriovenous fistulae (AVF) are the optimal form of vascular access for haemodialysis. AVFs typically require 6 to 8 weeks to “mature” from the time of surgery before they can be cannulated. Patients with end-stage renal disease needing urgent vascular access therefore traditionally require insertion of a tunnelled central venous catheter (TCVC). TCVCs are associated with high infection rates and central venous stenosis. Early cannulation synthetic arteriovenous grafts (ecAVG) provide a novel alternative to TCVCs, permitting rapid access to the bloodstream and immediate needling for haemodialysis. Published rates of infection in small series are low. The aim of this study is to compare whether TCVC ± AVF or ecAVG ± AVF provide a better strategy for managing patients requiring immediate vascular access for haemodialysis.

**METHODS/DESIGN:** This is a prospective randomised controlled trial comparing the strategy of TCVC ± AVF to ecAVG ± AVF. Patients requiring urgent vascular access will receive a study information sheet and written consent will be obtained. Patients will be randomised to receive either: (i) TCVC (and native AVF if this is anatomically possible) or (ii) ecAVG (± AVF). 118 patients will be recruited. The primary outcome is systemic bacteraemia at 6 months. Secondary outcomes include culture-proven bacteraemia rates at 1 year and 2 years; primary and secondary patency rates at 3, 6, 12 and 24 months; stenoses; re-intervention rates; re-admission rate; mortality and quality of life. Additionally, treatment delays, impact on service provision and cost-effectiveness will be evaluated.

**DISCUSSION:** This is the first randomised controlled trial comparing TCVC to ecAVG for patients requiring urgent vascular access for haemodialysis. The complications of TCVC are considered an unfortunate necessity in patients requiring urgent haemodialysis who do not have autologous vascular access. If this study demonstrates that ecAVGs provide a safe and practical alternative to TCVC, this could instigate a paradigm shift in nephrology thinking and access planning.

**TRIAL REGISTRATION:** This study has been approved by the West of Scotland Research Ethics



Committee 4 (reference no. 13/WS/0087, 28 August 2013) and is registered with the International Standard Randomised Controlled Trial Number Register (reference no. ISRCTN80588541 , 27 May 2014).

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