

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Cooper BA, Branley P, Bulfone L, et al. A randomized, controlled trial of early versus late initiation of dialysis. *N Engl J Med* 2010;363:609-19. DOI: [10.1056/NEJMoa1000552](https://doi.org/10.1056/NEJMoa1000552).

Supplementary Appendix:

Kt/V: is a number used to quantify dialysis adequacy (small molecule clearance) where:

K = dialyzer clearance of urea

t = dialysis time

V = patient's total body water (= urea distribution)

GFR calculated using Cockcroft and Gault Equation with BSA Correction

(ml/min/1.73m²):

$$\text{C+G GFR} = \frac{(140-\text{age}) \times \text{weight (kg)}}{\text{serum creatinine (mmol/L)} \times 814} \times \frac{1.73}{\text{BSA}} \times (0.85 \text{ if female})$$

Body Surface Area (BSA) Equation (m²):

$$\text{BSA} = 0.007184 \times \text{height(cm)}^{0.725} \times \text{weight(kg)}^{0.425}$$

GFR calculated using Modification of Diet in Renal Disease (MDRD) Equation

(ml/min/1.73m²):

$$\text{MDRD GFR} = 186 \times (\text{serum creatinine (umol/L)} / 88.4)^{-1.154} \times (\text{age})^{-0.203} \\ \times (0.742 \text{ if female}) \times (1.210 \text{ if of African descent})$$

Table 1. Reasons 159 Registered Patients Were Not Randomized

Reason	Number
Patient did not reach GRF 15mls/min/1.73m ² by the close of randomization	35
Died	20
Started dialysis before randomization - no reason given	39
Started dialysis before randomization because of uremia	20
Started dialysis before randomization because of uncontrolled fluid overload	6
Started dialysis before randomization because of septicemia	1
Started dialysis before randomization because of cardiac co-morbidity	1
Started dialysis before randomization because of major surgery	1
Patient withdrawal of consent	9
Sudden unexpected decline in GFR to <10 ml/min/1.73m ²	7
Patient unable to be followed up because of transfer to non-participating hospital	5
Physician discretion	4
Transplanted or planned transplant before randomization	4
Cancer	2
Reason not recorded	2
Unable to contact patient	2
Recovered renal function	1

Table 2: List of Protocol Violations.

Reason for not starting dialysis in assigned GFR range (protocol violations)	Randomized to early start group but started with GFR < 10ml/min/1.73m² (n=75)	Randomized to late start group but started with GFR >7ml/min/1.73m² (n=322)
Uremia	5	234
Physician discretion	10	25
Fluid overload	1	28
Delay in access creation	21	1
Patient refusal	13	3
Unavailability of resources	6	6
Delayed follow up	6	.
Sudden unexpected decline in GFR	6	.
Malnutrition	.	5
Hyperkalaemia	.	4
Malaise and fatigue	.	3
Sudden unexpected improvement in GFR	.	2
Other reasons*	7	11

*Reasons include: change in patients social circumstances (2), failed pre-emptive transplant overseas, emigration, transferred to a non-participating hospital, accidental randomization after starting dialysis, started early prior to major surgery, patient became un-contactable, acute myocardial infarction, unstable angina, severe hypertension, severe gout, peritonitis, intestinal perforation, neuropathy (2), pruritis and septicemia.