

The High-volume Haemodiafiltration vs High-flux Haemodialysis Registry Trial (H4RT) – Recruitment progress following QRI recommendations

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Background: End stage kidney disease (ESKD) affects around 65,000 people in the UK. Almost half of these people will have blood cleaning treatment known as haemodialysis (HD) or haemodiafiltration (HDF) at a hospital. In theory, HDF should remove toxins more effectively than HD, thus improving survival, infection rates and quality of life for patients. However, this has not been demonstrated in randomised controlled trials (RCT) therefore any benefit may be being cancelled out by other factors in the HDF treatment.

Methods/design: H4RT is a non-blinded RCT comparing the clinical and cost-effectiveness of high-volume HDF compared with high-flux HD in the treatment of ESKD. Patients are randomised 1:1, stratified by site, age and residual renal function. The primary analysis will be intention-to-treat using proportional hazards regression adjusting for variables used to stratify the randomisation.

Setting: Secondary care renal units in the UK. **Target population:** adult patients on in-centre, maintenance HD or HDF for ESKD. **Exclusion criteria:** lack of capacity to consent; clinician predicted life expectancy of less than 3 months; living kidney donor transplant or home dialysis scheduled within 3 months; prior intolerance of HDF; not suitable for high-volume HDF for other clinical reasons.

Intervention: high-volume HDF (aiming for ≥ 21 L of substitution fluid per session body surface area adjusted); **comparator=** high-flux HD.

The QuinteT Recruitment Intervention (QRI) has been integrated throughout the RCT to optimise recruitment by identifying difficulties as they occur and implement generic strategies to address them.

Recruitment processes are being explored with reviews of centres as they open and throughout recruitment.

Progress: The study opened to recruitment in November 2017 with a target of 1550 patients by end March 2021. As of 24 January 2020, there are 28 sites open to recruitment and 968 (62%) patients randomised. A further 4 sites are in set-up.

Feedback of QRI findings to support recruitment include 1) revisiting previously excluded satellite units to increase pool of eligible patients; 2) inviting as many eligible patients as possible in each site/satellite to take part; 3) encouraging PIs/clinicians and key clinical advocates for H4RT to discuss H4RT with eligible patients; 4) providing training and support to research nurses and renal staff in delivering body surface area-adjusted high-volume HDF; 5) discussing with high recruiting sites the potential to raise site recruitment targets.

We have run an investigator meeting, where site PIs, research and clinical staff attended a central educational training day to share learning on site-specific recruitment and clinical compliance. Additionally, the central trials team hold reviews every two months to discuss recruitment challenges and provide additional support where needed. The team provide sites with incentives, rewards, regular newsletters and social media updates celebrating success.

Conclusion

H4RT is one of the first 'efficient registry RCTs' in nephrology. Successful recruitment at 90% power will provide robust evidence to establish whether high-volume HDF is more effective at improving fatal and non-fatal cardiovascular and infection outcomes in people on haemodialysis.

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