Health Technology Assessment Programme

NHS National Institute for Health Research

HTA no 18/51

Extended duration haemodialysis

Introduction

The aim of the HTA Programme is to ensure that high quality research information on the effectiveness, costs and broader impact of health technology is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research are identified and prioritised to meet the needs of the NHS. Health technology assessment forms a substantial portfolio of work within the National Institute for Health Research and each year about fifty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include both primary research and evidence synthesis.

Research Question:

Does extended hours haemodialysis improve health and quality of life outcomes compared to conventional haemodialysis regimens, and is it cost effective?

1. **Intervention:** Extended duration haemodialysis (applicants to define and justify frequency and duration of sessions as well as timing and location; for example applicants to consider assessing in centre nocturnal haemodialysis and any other appropriate setting/timing).
2. **Patient group:** Adults requiring haemodialysis (applicants to define, justify and to detail potential subgroups for pre-specified subgroup analysis).
3. **Setting:** Places where haemodialysis is conducted (e.g. hospital, renal unit, satellite centre).
4. **Control:** Usual care consisting of 'conventional' in centre haemodialysis (e.g. 3 sessions per week of 3.5-5 hours of haemodialysis). Applicants to define and justify.
5. **Study design:** Randomised controlled trial with internal pilot (including stop/go criteria) to determine willingness and ability to recruit patients and staff, and to ascertain a meaningful difference in duration of dialysis between treatment groups. The study should also include process evaluation.
6. **Important outcomes:** Fatigue; Quality of life (EQ-5D); cardiovascular disease; vascular access; patient safety; mortality; cost-effectiveness.

   Other outcomes: Anxiety scores, physical health (SF-12), dialysis clearance, fluid removal on dialysis; impact on patient, family, friends and staff; ability to work and travel.
7. **Minimum duration of follow-up:** Applicants to define and justify.

NHS decision problem to be addressed by this research:

There are a growing number of people starting renal replacement therapy every year. With limited availability of organs for transplant the result is more people starting and remaining on dialysis. Although home dialysis is actively encouraged it is not always possible or available and overall take up is very low with the significant majority of patients attending hospital (or satellite centre) for their treatment, usually 3 times per week for 3-5 hours each time.

There is some evidence that extended duration haemodialysis might confer clinical benefits and be more acceptable and convenient for patients. Overall the quality of evidence to guide duration of haemodialysis sessions is lacking. Integrating extended duration dialysis into a busy dialysis day unit might be difficult but extending dialysis unit opening hours to offer extended duration sessions, potentially overnight, where there is some evidence of benefit, might address some of the issues.

A high quality adequately powered randomised trial to determine the potential benefits of extended duration haemodialysis, and in particular in centre nocturnal haemodialysis, is warranted to provide the evidence which is lacking to guide management in this expanding patient population. Co-production of study design with patients is regarded as particularly important for applications to this brief.

Making an application

If you wish to submit a Stage 1 application against this topic, the on-line application form can be found along with the details for this brief at www.nihr.ac.uk/funding-and-support/current-funding-opportunities/ The HTA Programme can be selected using the filters and the application should be submitted on-line no later than 1pm on the **26th September 2018** Applications will be considered by the HTA Funding Board at its meeting in **November**.

The guidance notes for this call can be found at: www.nihr.ac.uk/hta_st1_guidancenotes. The supporting information can be found at: www.nihr.ac.uk/hta_supportinfo.

IMPORTANT: For Stage 1 applications, if shortlisted, investigators will be given a minimum of **eight weeks to submit a Stage 2 proposal**. The Stage 2 proposal will be considered at the Funding Board in **March 2019**.

Applications received electronically after 1300 hours on the due date will not be considered.

Should you have any queries please contact us:
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