NightLife results lay summary

Study title: A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus standard care using a mixed method approach.

Who carried out the research?
The trial was sponsored by the University of Leicester (UoL), the Leicester Clinical Trials Unit (LCTU) over saw the trial and data management. The results of the trial were analysed in conjunction with the LCTU. The trial was funded by National Institute for Health and Care Research (NIHR) and received favourable ethical opinion from West Midlands – Edgbaston Research Ethics Committee.

What public involvement was there in the trial (how many people, what their relevant lived experience was and what they did)?
Patients and public were involved on the concept, scope and design of the trial from the very outset and for the duration of the trail. A specific haemodialysis Public and Patient Involvement (PPI) group was established to seek advice about the scope and design of dialysis trials. The group met four times over a two-year period and informed the concept, design (including outcomes) of this trial.

Madeleine Warren was a co-applicant for the trial and acted as a non-independent, non-voting, lay representative for the Trial Steering Committee (TSC). In addition to Warren, an independent expert patient joined the TSC. Together, they helped to review the data and contributed to the reporting and dissemination of the results.

Where and when did the trial take place?
The NightLife trial tool place at seven NHS trusts across the uk;

- Southern Health and Social Care Trust
- South Tees Hospitals NHS Foundation Trust
- Greater Glasgow Health Board
- University Hospitals of Leicester NHS Trust
- Kings College Hospitals NHS Foundation Trust
- Betsi Cadwaladr University Health Board
- Manchester University NHS Foundation Trust.

The first participant was randomised on 5th November 2021 at University Hospitals Leicester NHS Trust; the last participant was randomised on 7th October 2024 at Manchester University NHS Foundation Trust with the final follow-up taking place in April 2025. The trial will officially close on the 31st of July 2026, to enable adequate time to complete the embedded Study Within A Trial (SWAT).

Why was the research needed?
Haemodialysis can have extensive physiological, psychological and sociological impacts on patients. This is due to the side effects of haemodialysis and also the scheduling of treatment times, which results on patients ‘losing’ three days a week. Patient reported quality of life is low, with many patients unable to continue paid employment. Home haemodialysis, including dialysis overnight at home is one way of offering flexibility for patients on regular dialysis (in hospital during the day) but there are barriers for many patients. In-centre nocturnal dialysis involves patients dialysing for longer whilst there asleep, to provide longer dialysis sessions which replicates the functions of the kidneys for favourably along with the additional benefit of freeing up their time during the day.

What where the main questions asked?
The overall aim of the trial was to test the clinical and cost-effectiveness of thrice weekly, extended hours nocturnal dialysis compared to standard dialysis care thrice weekly during the day, with the following objectives.

1. To determine the willingness and ability to recruit and randomise patients to thrice weekly extended nocturnal dialysis during a 12-month internal pilot.
2. To measure the effect of extended hours in-centre nocturnal dialysis compared with daytime dialysis for patients with end-stage kidney disease on haemodialysis.
3. To measure the effect of extended hours in-centre nocturnal dialysis compared with daytime dialysis for patients with for patients with end-stage kidney disease on haemodialysis on terms of secondary outcome measures collected at 1, 3, and 6 months post randomisation.
4. To assess the acceptability of in-centre nocturnal dialysis to patients and staff.
5. To evaluate the cost effectiveness of extended hours in-centre nocturnal dialysis compared with daytime dialysis for patients with end0stage kidney disease within as NHS costing perspective.
6. To understand and address issues the undermine randomised controlled trials and informed consent during the QuinteT Recruitment Intervention.

Who participated in the trial?
100 participants were randomised, 57 to the nocturnal arm and 43 to the daytime arm. 11 participants withdrew which means 89 completed the trial.

What treatments or interventions did the participants receive?
Participants where randomised on a 1:1 basis to either:

Group A - Extended hours nocturnal haemodialysis (6-8hours of in-centre haemodialysis delivered overnight, 3 times per week for 6 months)

OR

Group B - Daytime haemodialysis (3.5-5 hours on in-centre haemodialysis, 3 times per week during the day for 6 months

What medical problems (adverse reactions) did the participants have?
There were 52 Serious Adverse Events (SAEs) reported in 24 participants. The most common being admission to hospital for a variety of unrelated symptoms.

What were the results of the trial?
The trial did not recruit the number of participants required to confirm a statistically significant result.

How has this study helped patients and researchers?
During the trial, irrespective of randomised treatment, participants received close monitoring of their condition to ensure they were receiving optimal medical treatment.
This trial can help researchers in the future by providing valuable safety data and contributing essential data for further meta-analysis.

Details of any further research planned
There are currently no plans for research for this specific trial.

Where can I learn more about this trial?
You can learn more about the NightLife trial by accessing the trial record at ISRCTN https://www.isrctn.com/ISRCTN11722317 which is a globally recognised trial registry, it ensures research transparency and allows patients and medical professionals to track trials from inception to completion.

Thank you to the trial participants

We would like to take this opportunity to thank all the trial participants for their support and participation in the NightLife trial. Their participation has been crucial and the results have given us important information that will help us to develop more new treatments for end-stage kidney disease.