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Does nocturnal haemodialysis improve heart disease for patients on dialysis?

Submission date
23/08/2021

Recruitment status
No longer recruiting

Registration date
11/08/2022

Overall study status
Completed

Last Edited
03/07/2024

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Heart disease is the leading cause of death for patients with kidney failure on dialysis. To stay alive, patients on haemodialysis have to have their blood cleaned 3 times a week for 4 hours in hospital by a machine. Whilst this keeps patients alive, having renal failure and being on dialysis leads to scarring in the heart which builds up over time causing the heart to fail, ultimately leading to death. The speed at which dialysis has to be done (over 4 hours) and the need to remove water quickly from these patients during dialysis are the major reasons why scarring in the heart builds up so quickly. If patients were able to have dialysis more slowly, over a longer period of time (e.g. overnight when they are asleep) this might slow or even reverse the scarring that builds up in their hearts and improve survival. It will also leave their days free to, hopefully, return to a more normal life.

The NIGHTLIFE-CMR sub-study will assess whether dialysing over a longer period of time (6-8 hours) overnight reduces levels of scarring in people's hearts (measured with MRI) compared to staying on standard daytime dialysis.

Who can participate?
Participants from the main NightLife study (ISRCTN87042063).

What does the study involve?
Participants will be offered the opportunity to attend the hospital for separate visits to have an MRI scan of their heart at baseline and 6 months to see if extended hours night-time dialysis is beneficial for patients' hearts and blood vessels. The scan will need to be organised on one of the days after their dialysis session to make sure the fluid levels in their body are stable. The MRI scan takes about 40 minutes during which time the participant will be lying within the MRI scanner. They will be asked to breathe in and out and hold their breath for short periods. Participants who have the MRI scan will also be asked to give some extra blood for testing at baseline and 6 months to measure for markers of heart disease in the blood. This will be the equivalent of 30ml (6 teaspoons) of blood taken at baseline and 6 months and will be taken when they are on dialysis. These test results will be analysed at the end of the study and will not be shared with the participant or alter their clinical care. This sub-study runs alongside the main NightLife study (ISRCTN87042063).

What are the possible benefits and risks of participating?
There are no guaranteed benefits to taking part in the study. All participants taking part in this study will also be helping to make a significant contribution to research into both daytime and night-time dialysis, which may improve future treatment. We hope that the results of the study will help us design improved treatments for other kidney patients in the future. With regard to risks, participants may find lying within the MRI scanner a little claustrophobic. However, the research staff will be in constant communication with the participant and the session can be stopped at any time. This scan does require an additional visit to the hospital on a different day from when they have dialysis, but this can be arranged at a convenient time for them. Participants will also be asked to give an extra blood sample for the purposes of the sub-study. However, this will be taken at the same time as the insertion and removal of their dialysis needles to ensure no further venepuncture is required.

Where is the study run from?
University of Leicester (UK)

When is the study starting and how long is it expected to run for?
January 2021 to September 2025

Who is funding the study?
British Heart Foundation
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Matthew Graham-Brown, mgb23@le.ac.uk
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
280452

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 280452, UOL0744

Study information

Scientific Title

NIGHTLIFE-CMR: A cardiac MRI sub-study Investigating the impact of in-centre nocturnal haemodialysis on cardiac structure and function

Acronym
NIGHTLIFE-CMR

Study objectives
This study will assess whether thrice weekly, extended hours nocturnal dialysis leads to improvements in measures of cardiovascular disease assessed with cardiac MRI compared to standard daytime haemodialysis. A sub-study of ISRCTN87042063.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/12/2020, West Midlands - Edgbaston Research Ethics Committee (The Royal College of Surgeons of Edinburgh, 85-89 Colmore Row, Birmingham, B3 2BB, UK; +44 (0)20 7104 8112; edgbaston.rec@hra.nhs.uk), REC ref: 20/WM/0275, CAG ref: 20/CAG/0136

Study design
Two-arm multi-centre randomized controlled trial as a cardiac MRI sub-study of the NightLife study (ISRCTN87042063)

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Haemodialysis, kidney failure

Interventions
Participants will be randomised to either:
1. Intervention arm where participants will receive 6 - 8 h of in-centre haemodialysis delivered overnight, 3 times per week for 6 months.
2. Standard care arm where participants will receive 3.5 - 5 h of in-centre haemodialysis, 3 times per week during the day for 6 months.

Processes relating to recruitment and randomisation are the same as for the main NightLife study.

This cardiac MRI sub-study is funded separately from the main NightLife study (British Heart Foundation, ref PG/20/10132, ISRCTN87042063) and will recruit 100 participants (50 from each randomised group) from the main NightLife study and will take place in a limited number of centres (i.e. 3 of the 18 centres participating in the main study). The sub-study will assess whether dialysing over a longer period of time (6-8 hours) overnight reduces levels of myocardial fibrosis (measured with MRI) compared to staying on conventional haemodialysis. At the centres where this sub-study is running, participants recruited to the NightLife study will have the opportunity to consent to undergo additional tests at the beginning and end of the study which will form the main outcomes from the sub-study.

Cardiac structure and function will be assessed by cardiac magnetic resonance imaging (CMR) and cardiac biomarkers levels pre- and post-intervention. Myocardial fibrosis will be characterised using native T1 mapping (cardiac MRI). Outcome data, including mortality, cardiovascular events and hospitalisation will be collected. Participants recruited at centres where this sub-study is running can take part in the main NightLife study without taking part in sub-study.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Global myocardial native T1 time measured by cardiac MRI at baseline and 6 months

Key secondary outcome(s))
1. Other prognostically powerful measures of cardiovascular disease assessed with cardiac MRI at baseline and 6 months
1.1. Left ventricular mass, volumes and ejection fraction
1.2. Peak systolic circumferential and longitudinal strain and early diastolic strain rates
1.3. Aortic stiffness assessed with aortic distensibility and aortic pulse wave velocity
1.4. Native T2 mapping
2. Myocardial fibriosis measured using blood test for high-sensitivity cardiac Troponin I, taken at the beginning and ends of dialysis sessions, at baseline and 6 months

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Participant in the main NightLife study (ISRCTN87042063)
2. Patients established on haemodialysis for ≥3 months (i.e. prevalent dialysis patients)
3. Aged ≥18 years
4. Able to give informed consent
5. Able to participate fully in the interventions and follow-up procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Currently on in-centre nocturnal dialysis, or less than 3 months since stopping
2. Less than 3 months since stopping extended daytime dialysis
3. Patients for whom extended dialysis is clinically indicated (e.g. calciphylaxis, pregnancy)
4. Scheduled for living donor kidney transplant
5. Plan to change dialysis modality or centre in the next 6-months
6. Life expectancy of <6-months
7. Current participation in an interventional trial with conflicting therapies or primary outcomes
8. Absolute contraindications to a cardiac MRI scan (CMR): non-conditional devices or implants; severe claustrophobia

Date of first enrolment
01/10/2021

Date of final enrolment
01/04/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Study participating centre
Queen Elizabeth University Hospital Glasgow
Govan Rd

Glasgow
United Kingdom
G51 4TF

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4.1	26/09/2023	03/07/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes