

Does nocturnal haemodialysis improve heart disease for patients on dialysis?

Submission date 23/08/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/08/2022	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/07/2024	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Prof James Burton, jb343@le.ac.uk

Kelly Parke, kelly.parke@uhl-tr.nhs.uk

Study website

<https://www.nightlifestudy.co.uk>

Contact information

Type(s)

Scientific

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

280452

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

Global myocardial native T1 time measured by cardiac MRI at baseline and 6 months

Secondary outcome measures

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 fibrosis measured using blood test for high-sensitivity cardiac Troponin I, taken at the beginning and ends of dialysis sessions, at baseline and 6 months

Overall study start date

01/01/2021

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

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**

England

Scotland

United Kingdom

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
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G51 4TF

Sponsor information

Organisation
University of Leicester

Sponsor details
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Research & Enterprise Division
University of Leicester
Leicester General Hospital
Gwendolen Road
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LE5 4PW
+44 (0)116 258 4099/258 4867
RGOsponsor@leicester.ac.uk

Sponsor type
University/education

Website
<https://www2.le.ac.uk/colleges/medbiopsych/research/researchgovernance>

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

Publication and dissemination plan

The CI will be responsible for ensuring that the results of the study are disseminated through peer review journals, conference presentations and local mechanisms at all participating centres irrespective of the outcome within six months after the final study report. Authorship on the manuscript will be determined by the CI according to contribution to the study after discussion

with the TSC, and according to the guidelines of leading medical journals. The study will be reported in line with the CONSORT statement, which is an evidence-based, minimum set of recommendations for reporting randomised trials.

Intention to publish date

30/04/2026

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
Protocol file	version 4.1	26/09/2023	03/07/2024	No	No