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In-centre extended nocturnal haemodialysis: the effects on cardiovascular structure and physical function

Submission date
16/07/2015

Recruitment status
No longer recruiting

Registration date
27/07/2015

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with established renal failure usually undergo haemodialysis for four hours, three times a week, in purpose-built units. This regime tends to place large strain on the heart and body. This strain can result in a number of different symptoms including dizziness, cramps and breathlessness. Haemodialysis itself causes the heart to enlarge and not work properly. In addition to this, most patients on dialysis are known to have very sedentary lifestyles due to the time commitments of their treatment, the nature of renal disease and related illnesses. Extending dialysis sessions has been shown as one way of reducing the symptoms patients' experience. This also reduces the strain on the patient's heart and may improve heart health. One potential way to provide longer sessions is to conduct the haemodialysis sessions overnight and this has the added benefit of freeing up time during the day. Currently the Leicester General Hospital is the only NHS centre in the UK to offer nocturnal haemodialysis sessions, in a hospital setting.
Some previous research by other groups has looked at how receiving dialysis overnight in dialysis units affects the heart. However they have not used the gold standard imaging techniques. Furthermore, no one has yet looked at the effects of nocturnal dialysis on physical function and activity levels. The aim of the study is to compare a thrice weekly in-centre nocturnal regime to the conventional four hour thrice weekly regime.
This exploratory study will use cardiac magnetic resonance imaging (the gold standard technique) to look at how nocturnal dialysis affects the heart. Additionally, we will use simple, validated methods to assess physical function and activity levels. We will collect data on body composition, nutrition, blood biochemistry and markers of inflammation, to look at associations between these results as well as with physical function and activity levels. We will also collect information on quality of life, sleep quality and symptom burden. All the outcomes collected will provide us with high quality or new information that will help in the design of larger studies in the future.

Who can participate?
Adult patients on haemodialysis for more than three months.

What does the study involve?
There are two groups of participants: the intervention group and the control group.
In the intervention group, participants interested in extended hours dialysis in a dialysis unit overnight will switch from conventional daytime treatment to extended treatment overnight.
The control group will be made of participants on conventional day time treatment, who are matched to intervention patients and do not want to undergo extended treatment overnight.

What are the possible benefits and risks of participating?
Patients who receive extended treatment times in the overnight haemodialysis programme may expect to see improvements in their physical and psychological health. There are no other anticipated benefits to taking part in the research.

Where is the study run from?
Leicester General Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2014 to July 2016

Who is funding the study?
Van Geest Heart and Cardiovascular Research Fund, Leicester (UK)

Who is the main contact?
Mr Darren Churchward
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UNOLE 0528

Study information

Scientific Title
Maintenance In-centre nocturnal haemoDialysis: a feasibility study iNvestIGating the effects on cardiac structure and pHysical funcTion in comparison to conventional treatment

Acronym
MIDNIGHT

Study objectives
1. Cardiac structure and function, as measured by CMR and NICOM, will improve in haemodialysis patients who switch from a conventional four hour thrice weekly regime to a thrice weekly in-centre nocturnal regime compared to patients who remain on conventional four hour thrice weekly dialysis.
2. Physical function, as measured by the short physical performance battery and sit-to-stand 60, will improve in haemodialysis patients who switch from a conventional four hour thrice weekly regime to a thrice weekly in-centre nocturnal regime compared to patients who remain on conventional four hour thrice weekly dialysis.
3. The time spent physically active, as measured by accelerometry, will improve in haemodialysis patients who switch from a conventional four hour thrice weekly regime to a thrice weekly in-centre nocturnal regime compared to patients who remain on conventional four hour thrice weekly dialysis.
4. Quality of life, as measured by validated questionnaires will improve in haemodialysis patients who switch from a conventional four hour thrice weekly regime to a thrice weekly in-centre nocturnal regime compared to patients who remain on conventional four hour thrice weekly

dialysis.
5. Body composition and nutritional status, as measured by bioelectrical impedance analysis and diet recall, will improve in haemodialysis patients who switch from a conventional four hour thrice weekly regime to a thrice weekly in-centre nocturnal regime compared to patients who remain on conventional four hour thrice weekly dialysis.
6. Inflammatory and biochemical markers including, IL-6, IL-10, CRP, phosphate, calcium, and other markers measured monthly, will improve in haemodialysis patients who switch from a conventional four hour thrice weekly regime to a thrice weekly in-centre nocturnal regime compared to patients who remain on conventional four hour thrice weekly dialysis.
7. Dialysis efficacy will improve in haemodialysis patients who switch from a conventional four hour thrice weekly regime to a thrice weekly in-centre nocturnal regime compared to patients who remain on conventional four hour thrice weekly dialysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands- Northampton, 09/07/2015, REC ref: 15/EM/0268

Study design
Non-randomized controlled feasibility trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Renal disorders; Subtopic: Renal disorders; Disease: All Renal disorders

Interventions
Intervention arm: Patients interested in extended hours dialysis in a dialysis unit overnight and consenting to participation in the trial will switch from conventional daytime treatment

Control arm: Patients on conventional day time treatment, who are matched to intervention patients and do not want to undergo extended treatment overnight, will be recruited.

Intervention Type
Other

Primary outcome measure
As this is a feasibility study designed to inform future trial development, no single primary outcome will be selected. All outcomes collected are listed below:
1. Left ventricular mass in grams (using cardiac MR)
2. Cardiac output and other haemodynamic variables measured using the noninvasive cardiac output monitor (NICOM)
3. Physical performance, specifically gait speed, balance, muscular power and muscular endurance, as assessed by the short physical performance battery and the sit-to-stand 60 tests.
4. Habitual activity levels as assessed by accelerometery
5. Quality of life and perceived physical function assessed using short form 12 questionnaire, palliative outcome scale-symptoms renal questionnaire, Pittsburgh sleep quality index questionnaire, functional assessment of chronic illness treatment fatigue questionnaire, Leicester dialysis patient physical activity questionnaire.
6. Diet quality assessed by either dietary recall interview or food diary
7. Markers of malnutrition, inflammation, cardiovascular dysfunction a and cardiovascular risk assessed by analysis of blood sample
8. Body composition (including lean tissue, fat tissue, fluid overload, body cell mass) assessed by bioimpedance spectroscopy (using body composition monitor)

Secondary outcome measures
Please see Primary outcome measures section.

Overall study start date
01/09/2014

Completion date
31/07/2016

Eligibility

Key inclusion criteria
1. Be a prevalent haemodialysis patient for more than three months
2. Age 18 years or older
3. Able and willing to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Unable to undergo CMR scanning (metal implants / prostheses, claustrophobia etc.)
2. Age <18 years
3. Unable or unwilling to give informed consent

Date of first enrolment
20/07/2015

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leicester
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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
Van Geest Heart and Cardiovascular Research Fund

Results and Publications

Publication and dissemination plan
We will look to publish data relating to all outcome measures, as well as a methodology paper of the study protocol. Results will be included in a research newsletter that is given to patients to inform them of developments made by our research team and promote the research we are doing.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	results	08/09/2016		Yes	No
HRA research summary			28/06/2023	No	No
Results article		31/10/2017	18/08/2023	Yes	No