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The Cardiac Uraemic fibrosis Detection in DiaLysis patiEnts study

Submission date	Recruitment status	[X] Prospectively registered
28/05/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/07/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/08/2018	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Patients with kidney failure treated with dialysis are at very high risk of heart disease which carries with it a high risk of death and a drastic impact on a patients quality of life. This can be due to the fact that kidney disease can cause enlargement of the heart (cardiomegaly); this in turn can result in abnormal heart rhythms (arrhythmia) which can be life threatening. This study will look at a new method of MRI scanning to detect changes in heart function and scarring of the heart muscle that happens in the first year of dialysis treatment.

Who can participate?
Adult kidney disease patients who have been treated with haemodialysis for less than a year.

What does the study involve?
Each participant will be asked to undergo ECG tracing (which records heart rate and rhythm), a MRI scan of the heart and blood tests at their first visit and then six months later. This is done to see if there are any changes that may lead to kidney failure.

What are the possible benefits and risks of participating?
There is no direct benefit in participating though it is hoped that this study will allow us to develop better tests and treatment plans to reduce the risk of heart disease in patients with kidney failure. Some patients find having an MRI scan a little suffocating but there are no other risks anticipated with the study.

Where is the study run from?
The study is being run between the Glasgow Renal and Transplant Unit, NHS Greater Glasgow and Clyde (UK) and the University of Glasgow (UK).

When is the study starting and how long is it expected to run for?
The study will start in June 2015 and will run for two years.

Who is funding the study?
Kidney Research UK

Who is the main contact?
Dr Patrick Mark
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Contact information

Type(s)
Scientific

Contact name
Dr Patrick Mark

Contact details
BHF Cardiovascular Research Centre
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Glasgow
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
The Cardiac Uraemic fibrosis Detection in DiaLysis patiEnts study: an observational cohort study

Acronym
CUDDLE

Study objectives
We hypothesise that cardiac fibrosis (scarring) can be seen on a MRI scan in patients treated with dialysis for kidney failure. We believe that this scarring progresses over the first year of dialysis treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee 3; 21/01/2014; 13/WS/0301

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Renal failure

Interventions
Each subject will have a heart tracing (ECG) performed before and after a haemodialysis session with some blood tests taken for research at the time of haemodialysis. The next day, subjects will undergo MRI scanning of the heart to look for any evidence of scar tissue. An ECG will be repeated at the time of MRI scanning. The ECGs, MRI scan of heart and blood tests will be repeated after 6 months to see if there have been any changes, which might be related to kidney failure.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Volume of myocardial fibrosis on cardiac MRI scanning. This will be measured by MRI scanning of the heart at baseline and on a follow up MRI 6 months later.

Secondary outcome measures
1. Change in serum brain natriuretic peptide
2. Simple correlations will be tested between presence/volume of fibrosis and serum markers of cardiac muscle enlargements/fibrosis and features of arrhythmia on ECG (heart tracing)

Measured at baseline and 6 months later

Overall study start date
01/06/2015

Completion date

01/06/2017

Eligibility

Key inclusion criteria
Adult patients who have been treated with haemodialysis for <1 year are eligible

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
35

Key exclusion criteria
1. Live donor transplant planned during the next 6 months
2. Predicted life expectancy <6months
3. Inability to give informed consent
4. Contraindications to MRI imaging (pacemaker, extreme claustrophobia)
5. Atrial fibrillation (makes gating of CMR images difficult)

Date of first enrolment
01/06/2015

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
BHF Cardiovascular Research Centre
Glasgow
United Kingdom
G12 8TA

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
c/o Maureen Travers
Tennent Institute
Western Infirmary
Glasgow
Scotland
United Kingdom
G11 6NT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Kidney Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/10/2017		Yes	No
HRA research summary			28/06/2023	No	No