

The Cardiac Uraemic fibrosis Detection in Dialysis patiEnts study

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

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
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Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Observational cohort study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

Scotland

Study participating centre

BHF Cardiovascular Research Centre

Glasgow

United Kingdom

G12 8TA

Sponsor information**Organisation**

NHS Greater Glasgow and Clyde (UK)

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

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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