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Evaluation of cardiac perfusion, structure and function in chronic liver and kidney disease

Submission date
01/07/2014

Recruitment status
No longer recruiting

Registration date
19/08/2014

Overall study status
Completed

Last Edited
06/04/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Patients with advanced kidney disease are much more likely to die of a heart attack compared to healthy people. This is partly due to this group of people being more likely to have, for example, high blood pressure and diabetes, known risk factors for developing heart disease. However, more importantly, it is also due to other non-traditional risk factors often seen in kidney patients, such as oxidative stress (damage to the body cells due to free radicals), inflammation and poor nutrition. Most patients with end stage chronic kidney disease (CKD) die from heart disease. Having end stage CKD directly affects heart muscle (the myocardium) and causes changes to happen in the tiny blood vessels (micro-circulation) of the heart. Although the link between end stage CKD and heart disease is well known, what isnt established is how earlier stage CKD may have on the circulation and muscle of the heart. If we knew more, we might be able to take steps to stop this damage from happening. Also, although there has not, to date, been much research in the area, having cirrhosis of the liver can also affect the micro-circulation of the heart and can lead to a condition called cirrhotic cardiomyopathy. Up to 50% of patients undergoing a liver transplant are found to have damage to their hearts. With this is mind, we want to do an initial study to see how badly both the blood circulation and the heart muscle is damaged by end stage CKD and liver disease, by using a new, non-invasive MRI technique called Arterial Spin Labelling (ASL). ASL-MRI is used to measure how well the blood flows within tissues and has been used to look at the blood circulation in both the brain and the heart before. We will use this technique to look at the micro-circulation of the heart in end stage CKD and compensated cirrhosis (where the liver is severely damaged but there are enough healthy cells so that it can still work properly). It is hoped that the information gathered from doing ASL-MRI will result in a greater understanding of the relationship between heart, kidney and liver disease and will help to reduce deaths from these chronic diseases.

Who can participate
Adults aged between 18 and 65 and either have end stage CKD or compensated cirrhosis.

What does the study involve?
Patients are invited to come to a single visit to the hospital. While there, they undergo a ASL-MRI scan of their heart. They also undergo a variety of other tests to measure, for example, blood pressure, arterial pressure, stroke volume (how much blood is being pumped with every beat)

and their level of advanced glycation end-products (AGES), harmful substances that can be a sign of heart disease.

What are the possible benefits and risks of participating?
This study will not benefit participants directly but the information we get from this study may help us understand what causes some of the complications of liver or kidney disease and therefore, in the future, to look at ways of helping prevent these from happening. The risk of having the ASL-MRI scan is no different to a normal MRI scan. Patients may feel claustrophobic during the scan but they will be able to stop the scan at any time if they feel uncomfortable. The other tests have very few risks or side effects. Slight discomfort may be felt when cuffs are placed round the finger, leg or neck when measuring blood pressure.

Where is the study run from?
Royal Derby Hospital (UK)

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

Who is funding the study?
1. University of Nottingham (UK)
2. Derby Hospitals NHS Trust (UK)
3. Fresenius Medical Care Ltd (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4

Study information

Scientific Title
Evaluation of cardiac perfusion, structure and function in chronic liver and kidney disease: A cross-sectional observational study

Study objectives
Patients with chronic liver disease and chronic kidney disease have significantly higher rates of cardiovascular mortality compared to the normal population. Currently, the evidence for cardiac structural and functional change in both conditions has been accrued through several different imaging modalities on patients with varied clinical characteristics, such as aetiology, stage and age. MRI is developing as the gold-standard modality for assessing cardiac morphology and function. It is widely used in the assessment of those with cardiomyopathy due to other aetiologies. Newer techniques have been developed which provide a quantitative assessment of ventricular function and myocardial perfusion without depending on geometric assumptions (unlike echocardiography), minimise movement artefact with respiratory and cardiac gating and obviate the need for an invasively administered contrast medium.

The trialists therefore intend to pilot a new technique to examine in detail the cardiac microcirculation of those with compensated cirrhosis and CKD3. They hypothesise myocardial perfusion will be impaired in these patients and may relate to the degree of cardiac structural and functional change as well as changes seen in the peripheral vascular system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northampton NHS Ethics Committee, 14/03/2014, ref: 14/EM/0085

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Cardiovascular disease as result of chronic liver and chronic kidney disease

Interventions
1. MRI scan
2. Finometry
3. Thoracic bioimpedance
4. Skin autofluorescence
5. Blood samples
6. Applanation tonometry

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Myocardial perfusion as measured by Cardiac ASL MRI in ml/min/100g

Secondary outcome measures
1. Cardiac strain and architecture as measured by PC-MRI
2. Thoracic bioreactance
3. AGE measurement
4. Pulse wave velocity
5. Non-invasive haemodynamics (BP, CO, SVR)
6. Baroreceptor sensitivity
7. Echocardiographic measure of ejection fraction, heart volumes
8. Serum markers of cardiac damage, endotoxin levels, renal, liver function, clotting, full blood count

Overall study start date
07/07/2014

Completion date
07/12/2014

Eligibility

Key inclusion criteria
1. Age above 18 and below 65 years
2. Able to give informed consent
And either:
3. CKD Stage 3b (eGFR> 30 and <44 ml/min) or
4. Compensated Cirrhotic Liver Disease proven radiologically or on biopsy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Known cardiac disease- previous myocardial infarction, angina, arrhythmias including AF, cardiac surgery, myocarditis, pericarditis or other non-specified cardiac conditions
2. Taking beta blockers, calcium channel blockers or other rate/rhythm controlling medication
3. Unstable CKD AKI Stage 1 or more or other unplanned hospital admission relating to their kidney disease in the last 30 days
4. Unstable CLD Clinical decompensation or other unplanned hospital admission relating to their liver disease in the last 30 days
5. For liver patients previous Transjugular Portosystemic Shunt (TIPSS) insertion
6. Pregnant, breastfeeding or intending pregnancy
7. Unable to give consent or understand written information
8. Contraindications to MRI pacemaker, metallic fragments or implants, known claustrophobia
9. Inability to sustain 20 minutes of light exercise
10. Diabetes

Date of first enrolment
07/07/2014

Date of final enrolment
07/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
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Head of Research Grants and Contracts
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Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name

Derby Hospitals NHS Trust (UK)

Funder Name
Fresenius Medical Care Ltd (UK)

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?
HRA research summary			28/06/2023	No	No