ISRCTN12301736 https://doi.org/10.1186/ISRCTN12301736

Renal Arterial Spin Labelling in chronic Kidney disease

Submission date	Recruitment status	[_] Prospectively registered
29/10/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/12/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2019	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
It has been suggested that increased oxidative stress is an important cause of the impaired function of blood vessels in chronic kidney disease (CKD), but this has not been studied in detail. In this context, oxidative stress means an increased production of highly reactive oxygen molecules that have the potential to impair the function of blood vessels and the flow of blood to the kidneys. In this study, we are investigating whether infusing the antioxidant vitamin C, which can reduce oxidative stress, improves blood vessel function, and increases blood flow to the kidneys.
Magnetic Resonance Imaging or MRI is a type of scan which allows us to get detailed pictures of internal organs. The advantage of this MRI is that it does not involve exposure to harmful radiation, and as far as we know, there are no long term health risks.
We have developed a type of MRI scan called Arterial Spin Labelling (or ASL) that looks at the blood flow to the kidneys. This is a new technology which is not carried out in clinical practice at the moment. We hope that in the future it will allow us to look at the blood flow (or perfusion) to the kidneys in people with kidney disease or transplants without exposing them to harmful radiation. The purpose of this study is to if the results from the ASL-MRI correlate with markers of kidney function and oxidative stress, and if kidney blood flow is improved by vitamin C.

Who can participate?
Three groups of people will be recruited. People with chronic kidney disease stages 3 5, people with vascular disease of the kidney, and people being assessed to act as a live kidney donor.

What does the study involve?
For people with chronic kidney disease and vascular disease of the kidney: You will attend the Glasgow Cardiovascular Research Centre next to the Western Infirmary Glasgow having fasted for around 6 hours. After discussing what the study involves, you will be asked to sign a consent form. Your height, weight and blood pressures will be measured and a health questionnaire taken. An infusion of 100ml normal saline will be given and blood samples taken. The ASL-MRI scan will then be carried out. An infusion of vitamin C will then be given and further blood samples taken. A further ASL-MRI scan will then be carried out.
For people acting as a live kidney donor: You will attend the Glasgow Cardiovascular Research Centre next to the Western Infirmary Glasgow after having fasted for around 6 hours. After

discussing what the study involves, you will be asked to sign a consent form. Your height, weight and blood pressures will be measured and a health questionnaire taken. Samples of blood and urine will be taken. The ASL-MRI scan will then be carried out.

What are the possible benefits and risks of participating?
There are no direct benefits to the participants, however the study may result in treatment which will improve cardiovascular function in people with kidney impairment, and help to develop new types of imaging which will be useful in people with kidney disease.
The risks for people with chronic kidney disease and kidney vascular disease are as follows: We will take blood and urine samples to ensure that your kidneys are working normally and that there is no sign of any other health problem of which you are unaware. We will take a small amount of blood from the vein in your arm which in some rare cases can result in minor bruising. The amount of blood taken does not pose any risks. A blood pressure cuff can cause discomfort for the very brief period of time it is inflated, and in extremely rare cases cause a bruise. Some studies have suggested that administration of vitamin C may cause kidney stones. To minimize any such risk, you should not take part in this study if you previously had a kidney stone or if you are already taking daily vitamin C supplements.
The risks for people acting as live kidney donors are as follows: We will take blood and urine samples to ensure that your kidneys are working normally and that there is no sign of any other health problem of which you are unaware. We will take a small amount of blood from the vein in your arm which in some rare cases can result in minor bruising. The amount of blood taken does not pose any risks. A blood pressure cuff can cause discomfort for the very brief period of time it is inflated, and in extremely rare cases cause a bruise.

Where is the study run from?
The British Heart Foundation Glasgow Cardiovascular Research Centre (UK).

When is study starting and how long is it expected to run for?
The study starts in August 2013 and is expected to run until February 2015. Each individual participant undergoes only one study visit, and will not be followed up after this.

Who is funding the study?
NHS Greater Glasgow and Clyde Renal Unit Endowment Fund and Darlindas Charity for Renal Research (UK).

Who is the main contact?
Dr Keith Gillis, Clinical Research Fellow
keithgillis@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Patrick Mark

Contact details
BHF GCRC
126 University Place
Glasgow

United Kingdom
G12 8TA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GN13CA117

Study information

Scientific Title
Renal arterial spin labelling in chronic kidney disease: a cross over study of vitamin C versus normal saline

Acronym
Kid-RASL

Study objectives
Renal perfusion measured by arterial spin labelling magnetic resonance imaging (ASL MRI) correlates with renal biomarkers, and serum and urine markers of oxidative stress, and perfusion is improved by ascorbic acid.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 29/04/2013, ref: 13/WS/0090

Study design
Single centre, non-randomised, cross over study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

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, Kidney perfusion, Magnetic resonance imaging

Interventions
Participants are given ascorbic acid 2000mg in 100ml 0.9% saline given intravenously by peripheral cannula over 10 minutes. There is no randomisation and follow up is for the duration of the study visit, that is around 1.5 hours.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin C

Primary outcome measure
Change in renal perfusion by ASL MRI, measured after saline and then after ascorbic acid

Secondary outcome measures
Biomarkers of oxidative stress both measured after saline and then after ascorbic acid
1. Total antioxidant capacity measured by colorimetric assay
2. Rate of reactive oxygen species generation measured by electron paramagnetic resonance

Overall study start date
05/07/2013

Completion date
01/02/2015

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Written informed consent
3. CKD - people with chronic kidney disease stages 3 - 5, with an eGFR 15-30ml/min
4. LKD - people being assessed to act as live kidney donors
5. RVD - people with renovascular disease documented on imaging and after assessment by a nephrologist

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
36

Key exclusion criteria
1. Known liver disease (alcoholic liver disease, hepatitis, cirrhosis)
2. Known HIV infection
3. Known recreational drug or alcohol abuse
4. Clinical signs of acute infection
5. Known pregnancy
6. Women of childbearing age are who are at risk of pregnancy
7. Metal prosthesis contraindicating MRI
8. Claustrophobia contraindicating MRI

Date of first enrolment
05/07/2013

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
BHF GCRC
Glasgow
United Kingdom
G12 8TA

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details

Dr Maureen Travers
R&D Management office
Western Infirmary
Tennent Institute
1st floor, 38 Church Street
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United Kingdom
G11 6NT

Sponsor type
Government

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Darlinda's Charity for Renal Research (UK)

Funder Name
NHS Greater Glasgow and Clyde Renal Unit Endowment Fund (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?
Results article	results	01/12/2016	22/01/2019	Yes	No
HRA research summary			28/06/2023	No	No