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Neutrophil Gelatinase Associated Lipocalin as a predictor of acute kidney injury post coronary angiogram

Submission date
26/08/2011

Recruitment status
No longer recruiting

Registration date
13/03/2012

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
In Northern Ireland the rising number of patients with both chronic kidney disease (CKD) and heart disease is explained by many risk factors. These include age, high blood pressure, diabetes and obesity. Around 6000 coronary dye tests are performed each year in Northern Ireland. 20% of patients tested will have CKD and are at high risk of kidney damage due to the harmful dye used (contrast-induced nephropathy - CIN). Contrast dye is toxic to the kidney. Unfortunately there is no alternative to it and the number of patients who develop this complication is set to rise.

Acute kidney injury (AKI) is best avoided; once developed it dramatically increases risk of death, length of hospital stay and healthcare costs. Current tests fail to detect early AKI and there is a need for new markers of kidney damage. Neutrophil gelatinase associated lipocalin (NGAL) has the potential to detect AKI within a few hours of onset; we aim to study it in a high-risk CKD population.

This study aims to find out whether NGAL could be a useful marker of early CIN and see if it can predict severity of CIN, and to see if NGAL could be used to identify those at high risk of CIN.

Who can participate?
Patients at high risk of CIN will be identified prior to cardiac catheterisation at Craigavon Area Hospital between October 2011 and August 2013. All patients over the age of 18 with existing chronic renal failure, as shown by abnormal blood tests before the dye test, will be invited to take part. Men and women will both be invited.

What does the study involve?
A fluid drip will be given to help protect kidney function before the dye test. Blood samples will be collected directly before and after the dye test, and at 2, 4, 6, 24 and 48 hour time-points. Additional blood will be stored for possible future testing.

What are the possible benefits and risks of participating?
New markers to detect AKI early would help to treat patients who develop AKI sooner. If realised, this research has the potential to dramatically increase the safety of coronary dye testing and could greatly benefit patients both in Northern Ireland and further afield. The only risk to patients will be that of serial blood sampling, which may cause minor bleeding, pain or bruising. This will be reduced by using the smallest needle possible. All patients will have the same treatment.

Where is the study run from?
Craigavon Area Hospital (UK).

When is the study starting and how long is it expected to run for?
The study will run from October 2011 to August 2013.

Who is funding the study?
RANDOX laboratories.

Who is the main contact?
Dr Michael Connolly
Research Fellow
Cardiac Research
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1.1 19/08/2011

Study information

Scientific Title
Neutrophil Gelatinase Associated Lipocalin (NGAL) as a predictor of acute kidney injury post coronary angiogram: a cohort observational study

Study objectives
Raised levels of NGAL at 4 hours post contrast angiogram will predict acute kidney injury, as evidenced by a rise in creatinine > 25% at 48 hours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Cohort observational study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Chronic Renal Disease

Interventions
Samples for serum and urine NGAL, serum cystatin C and serum creatinine will be collected directly pre- and post-contrast angiogram, and at 2, 4, 6, 24 and 48 hr time-points to allow time course analysis post catheterisation.

Patients will be followed up at 30 days and 1 year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Post procedure biomarker elevation diagnostic for acute kidney injury

Secondary outcome measures
Major cardiac adverse events (MACE) at 30 days and one year:
1. Myocardial infarction
2. Stroke
3. Heart failure hospitalisation
4. Death

Overall study start date
15/10/2011

Completion date
03/08/2013

Eligibility

Key inclusion criteria
1. Age > 18 years
2. Presenting for angiogram with known chronic kidney disease (CKD) [glomerular filtration rate (GFR) < 60mls/min]

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Myocardial infarction (MI) or acute coronary syndrome within previous 6 weeks
2. Hospitalisation within previous 6 weeks
3. Decompensated heart failure
4. Inability to give informed consent

Date of first enrolment
15/10/2011

Date of final enrolment
03/08/2013

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Cardiology Unit
Portadown
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Sponsor information

Organisation
Randox Laboratories (UK)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Randox Laboratories (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	01/02/2018	18/01/2019	Yes	No