

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

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| Submission date 26/08/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 13/03/2012 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 18/01/2019 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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

Craigavon Area Hospital

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Radox 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 |