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Predicting safe patient discharge post percutaneous revascularisation

Submission date
30/04/2012

Recruitment status
No longer recruiting

Registration date
11/06/2012

Overall study status
Completed

Last Edited
07/04/2016

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
Acute coronary syndromes are conditions where decreased blood flow in the blood vessels supplying the heart (the coronary arteries) cause part of the heart muscle to be unable to function properly or to die. For example, angina is chest pain that occurs when the coronary arteries become hardened and narrowed, restricting the heart's blood supply. A myocardial infarction (heart attack) occurs when the heart's blood supply is suddenly blocked, usually by a blood clot. In the last 20 years stenting (also known as Percutaneous Coronary intervention or PCI) has revolutionised the treatment of angina and heart attack, improving prognosis and symptoms for thousands of patients. The procedure involves widening the coronary artery using a balloon catheter then placing a small mesh tube called a stent into the artery. Day case stenting is of increasing interest as it has been shown to be safe and cost saving. Patients are monitored for 6 hours after stenting, after which time complications have been shown to be very rare. However, occasionally a patient may suffer a heart attack following stenting, mainly due to a complication of the procedure. Sometimes this can be 'silent', i.e. without any symptoms. Special blood tests for biomarkers can be used to detect injury following stenting and have been of increasing interest over the last few years. An ideal biomarker would indicate if there was damage to the heart very soon after the injury and help to guide decisions with regard to patient discharge. Therefore, the aim of this study is to investigate the levels of such biomarkers during and after stenting to see if they can be used to predict adverse patient outcomes.

Who can participate?
Any patient over 18 years old presenting for day case stenting for chronic stable angina, acute coronary syndrome or myocardial infarction

What does the study involve?
Patients have blood samples taken to analyse for biomarkers at 0, 4, 6 and 24 hours after stenting, and receive a telephone call at 30 days and one year after stenting to assess for any adverse outcomes (e.g., myocardial infarction, stroke, heart failure, death).

What are the possible benefits and risks of participating?
There is no immediate direct benefit from taking part in this study as the results will not be

available until the study finishes. The information obtained will help improve our understanding of heart muscle damage during stenting procedures which it is hoped will eventually lead to improvements in this treatment for other future patients. You will be required to provide a sample of blood on three occasions. Occasionally, individuals may develop some local bruising and/or discomfort at the site of blood sampling.

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

When is the study starting and how long is it expected to run for?
April 2010 to July 2012

Who is funding the study?
Randox Laboratories (UK)

Who is the main contact?
Dr Michael Connolly
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
1.1 16/02/2010

Study information

Scientific Title
Predicting safe patient discharge post percutaneous revascularisation: an observational study

Study objectives
1. Normal levels of novel biomarkers of myocardial necrosis at 6 hours post procedure (fatty acid binding protein [FABP], glycogen phosphorylase isoenzyme BB [GPBB], myoglobin/carbonic

anhydrase 3 ratio, high-sensitivity [hs] troponin T) will predict normal 24-hour 4th generation Troponin T and creatine kinase (CK) levels post percutaneous revascularisation. This represents the null hypothesis. This will also predict those at low risk of cardiac events at 30 days and 1 year. 2. Prediction of elevated 24-hour troponin and CK levels by novel biomarkers of myocardial necrosis will be additive to that provided by clinical factors alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI), 08/03/2010, REC ref: 10 /NIR03/2

Study design
Cohort observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Ischaemic heart disease patients presenting for PCI

Interventions
Patients will have blood samples for biomarkers taken at 0, 4, 6 and 24 hours following stenting, and receive a telephone call at 30 days and one year following stenting to assess for adverse outcomes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Post procedure biomarker elevation diagnostic for Type 4a myocardial infarction

Key secondary outcome(s))
1. Major Adverse Cardiac Events (MACE) at 30 days and 1 year
1.1. Myocardial infarction
1.2. Stroke
1.3. Target vessel revascularisation
1.4. Heart failure hospitalisation
1.5. Death

Completion date
01/07/2012

Eligibility

Key inclusion criteria
1. Aged over 18 at enrolment
2. Undergoing Percutaneous Coronary Intervention (PCI) for chronic stable angina or as part of staged procedure following acute coronary syndrome (ACS)/myocardial infarction (MI) (index event >14 days previously)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Terminal malignancy
2. Inability to give informed consent due to impaired mental capacity
3. ACS/chest pain at admission/MI within last 14 days

Date of first enrolment
01/04/2010

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Craigavon Area Hospital
Portadown
United Kingdom
BT68 5QQ

Sponsor information

Organisation
Randox Laboratories (UK)

ROR
https://ror.org/04cte7x29

Funder(s)

Funder type
Industry

Funder Name
Randox Laboratories (UK)

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes