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RApid Diagnosis And Risk stratification of Acute Coronary Syndrome with novel biochip array

Submission date	Recruitment status	[ ] Prospectively registered
08/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/02/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2017	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
5.2

Study information

Scientific Title
RApid Diagnosis And Risk stratification of Acute Coronary Syndrome with novel biochip array: an observational cohort study

Acronym
RADAR-ACS

Study objectives
Measurement at 4 or 6 hours after symptom onset of a panel of early biomarkers of myocardial necrosis and plaque instability with a biochip assay array will be superior to measurement of the current gold standard diagnostic assay for myocardial infarction, Troponin T in patients presenting with acute coronary syndrome (ACS).

This biomarker array will also demonstrate greater independent predictive accuracy than troponin for recurrent cardiac events at 30 days and 1 year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI) approved on 08/05/2009 (ref: 09/NIR01/22). Protocol revision (version 5.2) and subsequent favourable opinion given on 11/11/2009.

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Acute coronary syndrome

Interventions
Patients will have blood sampled at admission then subsequently at time intervals 1, 2, 3, 6, 12 and 24 hours after admission. Blood will be spun and serum/plasma aliquoted then frozen at -80 degrees celsius until batch analysis. Analysis with a biochip panel consisting of Troponin I, Heart type fatty acid binding protein, Glycogenphosphorylase BB, Myoglobin, Carbonic anhydrase III and creatine kinase myocardial bands (CKMB) will be compared with 4th and 5th generation troponin T assays at each time point.

Intervention Type
Device

Primary outcome(s)
1. Sensitivity and specificity of investigational biomarkers when compared to troponin T at two prespecified time points after symptom onset: 4 hours, 6 hours
2. Major adverse cardiac events (MACE) defined as in hospital reinfarction (defined as further clinical signs and/or symptoms and greater than or equal to 20% increase in Troponin value 6 - 9 hours after the event), stroke, revascularisation, further admission with ACS heart failure hospitalisation, death

Key secondary outcome(s))

1. Bleeding complications (assessed according to the TIMI bleeding classification)
2. In hospital revascularistion. Within this subset presenting coronary anatomy and revascularisation type will be assessed
3. Length of hospital stay

Completion date
04/08/2012

Eligibility

Key inclusion criteria
Consecutive male and female patients over 18 years of age with a clinical diagnosis of possible acute coronary syndrome.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable to provide informed consent
2. Terminal malignancy
3. Patient received anticogulant treatment or fibrinolysis prior to enrolment

Date of first enrolment
27/10/2009

Date of final enrolment
04/08/2012

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Craigavon Area Hospital
Portadown
United Kingdom
BT63 5QQ

Sponsor information

Organisation
Southern Health and Social Care Trust (UK)

ROR
https://ror.org/02fjtnt35

Funder(s)

Funder type
Industry

Funder Name
Randox Laboratories (UK)

Funder Name
Southern Health and Social Care Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration