

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Irene Knox

Contact details
Craigavon Area Hospital
68 Lurgan Road
Portadown
United Kingdom
BT63 5QQ

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.

Primary study design

Observational

Study design

Observational cohort study

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, Glycogen phosphorylase 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 revascularisation. 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 anticoagulant 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
Radox 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