

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Cohort study

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

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 measure

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

Secondary outcome measures

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

Overall study start date

27/10/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

650

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

Northern Ireland

United Kingdom

Study participating centre

Craigavon Area Hospital

Portadown

United Kingdom

BT63 5QQ

Sponsor information

Organisation

Southern Health and Social Care Trust (UK)

Sponsor details

Craigavon Area Hospital

68 Lurgan Road

Portadown

Northern Ireland

United Kingdom

BT63 5QQ

Sponsor type

Hospital/treatment centre

Website

<http://www.southerntrust.hscni.net/>

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

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