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Coronary intervention dose reduction & image quality survey

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2015	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436165538

Study information

Scientific Title
Coronary intervention dose reduction & image quality survey

Study objectives
To evaluate the potential for reducing staff and patient X-ray dose during interventional coronary procedures (opening up blocked sections of coronary blood vessels) exploiting the improved technical properties of a new design of cardiac x-ray imaging system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Cardiovascular: Coronary disease

Interventions
Not provided at time of registration

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Measurement of X-ray dose (via average DAP rates) - endpoint to establish the potential radiation dose savings to patients and staff in interventional coronary procedures.

2. Measurements of clinical image quality using a scoring protocol - endpoint to verify that an appropriate level of clinical image quality can be maintained following dose reduction.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2005

Completion date
01/03/2008

Eligibility

Key inclusion criteria
Any patient scheduled for coronary intervention is in principal eligible for inclusion as participant in the study, subject to the appropriate consent conditions.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300 in total including 150 controls

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2005

Date of final enrolment
01/03/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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